

16.2.7.1 Adverse Events Legend Page

Category	Abbreviation	Text
Action - Study Vaccine Dose	NA	Not applicable
	P	Investigational product withdrawn
Action - Subject	TC	Concomitant drug treatment given
	TCN	Concomitant non-drug treatment given
	W	Withdrawn from study
Cause of AE	CD	Concomitant drug treatment
	CND	Concomitant non-drug treatment
	O	Other
Outcome	F	Fatal
	N	Not recovered/not resolved
	R	Recovered/resolved
	RS	Recovered/resolved with sequelae
	RG	Recovering/resolving
	UNK	Unknown
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
GENRL	General disorders and administration site conditions	

16.2.7.1 Adverse Events Legend Page

Category	Abbreviation	Text
	HEPAT	Hepatobiliary disorders
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

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16.2.7.1.IA1 Adverse Events Legend Page

Category	Abbreviation	Text
Action - Study Vaccine Dose	N	No other action
	NA	Not applicable
	O	Other action taken
	UNK	Unknown
	P	Investigational product withdrawn
Action - Subject	TC	Concomitant drug treatment given
	TCN	Concomitant non-drug treatment given
	W	Withdrawn from study
Cause of AE	CD	Concomitant drug treatment
	CND	Concomitant non-drug treatment
	O	Other
Outcome	F	Fatal
	N	Not recovered/not resolved
	R	Recovered/resolved
	RS	Recovered/resolved with sequelae
	RG	Recovering/resolving
	UNK	Unknown
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders

16.2.7.1.IA1 Adverse Events Legend Page

Category	Abbreviation	Text
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
	HEPAT	Hepatobiliary disorders
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

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16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Vaccine Group	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
BNT162b1	18-55	10 µg	C4591001 1001 10011004	1	04MAY2020	Redness (svt)	N		N	N	N	N	N		
						Swelling (svt)	N		N	N	N	N	N		
						Pain at the injection site	Mild		N	N	N	N	N	04MAY2020	1
				2	26MAY2020	Redness (svt)	N	N			N	N	N		
						Swelling (svt)	N	N			N	N	N		
						Pain at the injection site	Mild	N			N	N	N	26MAY2020	1
C4591001 1001 10011006	18-55	10 µg	C4591001 1001 10011006	1	06MAY2020	Redness (svt)	N		N	N	N	N			
						Swelling (svt)	N		N	N	N	N	N		
						Pain at the injection site	N		N	N	N	N	N		
				2	27MAY2020	Redness (svt)		N		N	N	N			
						Swelling (svt)		N		N	N	N			

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site		N		N	N	N			
			C4591001 1001 10011007	1	06MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	06MAY2020	1
				2	28MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	28MAY2020	1
			C4591001 1001 10011008	1	06MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	Mild	N	N	N	N	08MAY2020	2
				2	27MAY2020	Redness (svt)	N	N	N		N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N		N	N	N		
						Pain at the injection site	N	Mild	Mild		N	N	N	29MAY2020	2
			C4591001 1001 10011009	1	06MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	27MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	28MAY2020	1
			C4591001 1002 10021003	1	04MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	04MAY2020	1

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	26MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	29MAY2020	4
			C4591001 1002 10021004	1	04MAY2020	Redness (cu)		2							
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	26MAY2020	Redness (cu)		1							
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)	1	1	1						
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	27MAY2020	2

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
						1	2	3	4	5	6	7			
C4591001 1002 10021007			1	06MAY2020	Redness (svt)	N	N	N		N	N	N			
					Swelling (svt)	N	N	N		N	N	N			
					Pain at the injection site	N	N	N		N	N	N			
			2	26MAY2020	Redness (svt)	N	N	N	N	N	N	N			
					Swelling (svt)	N	N	N	N	N	N	N			
					Pain at the injection site	N	Mild	N	N	N	N	N	27MAY2020	1	
C4591001 1002 10021009			1	06MAY2020	Redness (svt)	N	N	N	N	N	N	N			
					Swelling (svt)	N	N	N	N	N	N	N			
					Pain at the injection site	Mild	Mild	N	N	N	N	N	07MAY2020	2	
			2	26MAY2020	Redness (cu)	1									
					Redness (svt)	N	N	N	N	N	N	N			
					Swelling (svt)	N	N	N	N	N	N	N			

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	Mod	Mild	Mild	N	N	N	N	28MAY2020	3
			C4591001 1002 10021011	1	06MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	06MAY2020	1
				2	26MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	26MAY2020	1
			C4591001 1002 10021012	1	05MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	26MAY2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1002 10021013	1	06MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	07MAY2020	2
				2	26MAY2020	Redness (cu)	4	2	1	1					
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	29MAY2020	4
		20 µg	C4591001 1001 10011067	1	01JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	22JUL2020	Pain at the injection site	N	Mild	Mild	Mild	Mild	N	N	05JUL2020	4
						Redness (svt)	N	N	N	N		N			
						Swelling (svt)	N	N	N	N		N			
						Pain at the injection site	Mild	Mild	Mild	Mild		N		25JUL2020	4
			C4591001 1001 10011068	1	29JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)		5						30JUN2020	1
						Swelling (svt)	N	Mild	N	N	N	N	N		
						Pain at the injection site	Mild	Mod	N	N	N	N	N	30JUN2020	2
				2	20JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	N	N	N	N	22JUL2020	3

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
			C4591001 1001 10011070	1	01JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	22JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1001 10011071	1	01JUL2020	Redness (svt)	N	N	N	N	N		N		
						Swelling (svt)	N	N	N	N	N		N		
						Pain at the injection site	N	N	N	N	N		N		
				2	22JUL2020	Redness (cu)	1								
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)	2	2							

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mild	Mod	N	N	N	N	N	23JUL2020	2
		C4591001 1001 10011076	1	01JUL2020	Redness (svt)	N	N	N		N	N	N		
					Swelling (cu)		5						02JUL2020	1
					Swelling (svt)	N	Mild	N		N	N	N		
					Pain at the injection site	Mild	Mod	Mild		N	N	N	03JUL2020	3
			2	21JUL2020	Redness (svt)	N	N	N		N	N	N		
					Swelling (svt)	N	N	N		N	N	N		
					Pain at the injection site	N	Mild	Mild		Mild	N	N	25JUL2020	4
		C4591001 1002 10021079	1	29JUN2020	Redness (cu)		1							
					Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		

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Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	21JUL2020	Pain at the injection site	Mild	Mild	N	N	N	N	N	30JUN2020	2
						Redness (cu)		1							
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	22JUL2020	1
			C4591001 1002 10021080	1	01JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	21JUL2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			
						Pain at the injection site	N	Mild	Mild	N	N	N		23JUL2020	2

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d		
							1	2	3	4	5	6	7				
C4591001 1002 10021081				1	01JUL2020	Redness (svt)	N		N	N	N	N	N				
						Swelling (cu)	14						01JUL2020	1			
						Swelling (svt)	Mod		N	N	N	N	N				
C4591001 1002 10021082				1	01JUL2020	Redness (svt)	N	N	N	N	N	N	N				
						Swelling (svt)	N	N	N	N	N	N	N				
						Pain at the injection site	Mild	Mild	Mild	N	N	N	N	03JUL2020	3		
				2	21JUL2020	Redness (cu)	2	2	2	2	2	3					
						Redness (svt)	N	N	N	N	N	N	N				

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
						1	2	3	4	5	6	7			
					Swelling (cu)	4									
					Swelling (svt)	N	N	N	N	N	N	N			
					Pain at the injection site	Mild	Mild	Mild	N	N	N	N	23JUL2020	3	
			C4591001 1002 10021084	1	29JUN2020	Redness (svt)	N	N	N	N	N	N			
					Swelling (svt)	N	N	N	N	N	N	N			
					Pain at the injection site	Mild	Mild	N	N	N	N	N	30JUN2020	2	
				2	21JUL2020	Redness (svt)	N	N	N		N	N			
					Swelling (svt)	N	N	N		N	N	N			
					Pain at the injection site	Mild	Mild	N		N	N	N	22JUL2020	2	
			C4591001 1002 10021085	1	29JUN2020	Redness (svt)	N	N	N	N		N	N		
					Swelling (svt)	N	N	N	N		N	N			

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	Mild	N	N	N		N	N	29JUN2020	1
				2	21JUL2020	Redness (svt)	N	N		N	N	N	N		
						Swelling (cu)	7							21JUL2020	1
						Swelling (svt)	Mild	N		N	N	N	N		
						Pain at the injection site	N	N		Mild	N	N	N	24JUL2020	1
			C4591001 1002 10021087	1	01JUL2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			
						Pain at the injection site	Mild	Mild	Mild	Mild	N	N		04JUL2020	4
				2	21JUL2020	Redness (cu)	1	1		1	1				
						Redness (svt)	N	N		N	N	N	N		
						Swelling (cu)	1								
						Swelling (svt)	N	N		N	N	N	N		
						Pain at the injection site	Mild	Mild		Mild	Mild	Mild	N	26JUL2020	6

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
						1	2	3	4	5	6	7			
		30 µg	C4591001 1001 10011011	1	11MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mod	N	N	N	N	N	12MAY2020	1
				2	01JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mod	Mod	Mild	Mild	N	N	N	04JUN2020	4
			C4591001 1001 10011012	1	13MAY2020	Redness (cu)		7						14MAY2020	1
						Redness (svt)	N	Mild	N	N	N	N	N		
						Swelling (cu)		7	5	3				15MAY2020	2
						Swelling (svt)	N	Mild	Mild	N	N	N	N		
						Pain at the injection site	N	Mod	N	N	N	N	N	14MAY2020	1
				2	03JUN2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	Mild	Mild	Mild	N	N	07JUN2020	4
			C4591001 1001 10011015	1	11MAY2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			
						Pain at the injection site	N	Mild	N	N	N	N		12MAY2020	1
				2	01JUN2020	Redness (svt)	N		N	N	N	N			
						Swelling (svt)	N		N	N	N	N			
						Pain at the injection site	Mild		N	N	N	N		01JUN2020	1
			C4591001 1001 10011017	1	13MAY2020	Redness (svt)	N	N	N	N		N	N		
						Swelling (svt)	N	N	N	N		N	N		
						Pain at the injection site	N	Mod	N	N		N	N	14MAY2020	1

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	03JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	Mild	N	N	N	06JUN2020	4
			C4591001 1001 10011019	1	13MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	14MAY2020	2
				2	03JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	Mild	N	N	07JUN2020	5
			C4591001 1001 10011020	1	13MAY2020	Redness (cu)		20	20	20				16MAY2020	3
						Redness (svt)	N	Mod	Mod	Mod	N	N	N		
						Swelling (cu)		20	20					15MAY2020	2

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	Mod	Mod	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	16MAY2020	4
				2	03JUN2020	Redness (cu)		17	19	20				06JUN2020	3
						Redness (svt)	N	Mod	Mod	Mod	N	N	N		
						Swelling (cu)		17						04JUN2020	1
						Swelling (svt)	N	Mod	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	06JUN2020	4
			C4591001 1001 10011024	1	13MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	16MAY2020	4
				2	03JUN2020	Redness (svt)	N	N	N	N		N	N		
						Swelling (svt)	N	N	N	N		N	N		
						Pain at the injection site	N	Mod	Mild	Mild		N	N	06JUN2020	3

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
						1	2	3	4	5	6	7			
C4591001 1002 10021006			1	11MAY2020	Redness (svt)	N	N	N	N	N	N	N			
					Swelling (svt)	N	N	N	N	N	N	N			
					Pain at the injection site	Mild	Mild	N	N	N	N	N	12MAY2020	2	
					2	02JUN2020	Redness (cu)			13	14	18	10	07JUN2020	4
							Redness (svt)	N	N	Mod	Mod	Mod	Mild	N	
							Swelling (cu)					18		06JUN2020	1
							Swelling (svt)	N	N	N	N	Mod	N	N	
Pain at the injection site	Mild	Mild	Mild	Mild	Mild	Mild	N	07JUN2020	6						
C4591001 1002 10021014	1	13MAY2020	Redness (cu)	1	1										
			Redness (svt)	N	N	N	N	N	N						
			Swelling (cu)	1	1										
			Swelling (svt)	N	N	N	N	N	N						

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	Mild	Mod	Mild	N	N	N		15MAY2020	3
				2	02JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mod	Mild	Mild	Mild	Mild	N	07JUN2020	6
			C4591001 1002 10021015	1	11MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mod	N	N	N	N	N	12MAY2020	1
				2	02JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	03JUN2020	1
			C4591001 1002 10021017	1	13MAY2020	Redness (cu)				3					

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mod	N	N	N	N	N	14MAY2020	2
				2	02JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)	5	3						02JUN2020	1
						Swelling (svt)	Mild	N	N	N	N	N	N		
						Pain at the injection site	Mod	Mild	N	N	N	N	N	03JUN2020	2
			C4591001 1002 10021020	1	13MAY2020	Redness (svt)	N	N	N		N	N	N		
						Swelling (svt)	N	N	N		N	N	N		
						Pain at the injection site	Mild	Mod	Mild		N	N	N	15MAY2020	3
				2	02JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	Mild	N	N	06JUN2020	5

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d		
							1	2	3	4	5	6	7				
Placebo	18-55	Placebo	C4591001 1001 10011005	1	06MAY2020	Redness (svt)	N	N	N	N	N	N	N				
						Swelling (svt)	N	N	N	N	N	N	N				
						Pain at the injection site	N	N	N	N	N	N	N				
						C4591001 1001 10011066	1	29JUN2020	Redness (cu)		1	2	2				
			Redness (svt)	N	N				N	N	N	N	N				
			Swelling (svt)	N	N				N	N	N	N	N				
			Pain at the injection site	N	N				N	N	N	N	N				
			C4591001 1001 10011066	1	29JUN2020	Redness (svt)	N	N	N	N	N	N	N				
Swelling (svt)	N	N				N	N	N	N	N							
Pain at the injection site	N	N				N	N	N	N	N							
			C4591001 1001 10011066	2	20JUL2020	Redness (svt)	N	N	N	N	N	N					
Swelling (svt)	N	N				N	N	N	N								

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	N	N	N	N	N			
			C4591001 1001 10011069	1	01JUL2020	Redness (svt)	N	N		N		N	N		
						Swelling (svt)	N	N		N		N	N		
						Pain at the injection site	N	N		N		N	N		
				2	22JUL2020	Redness (svt)	N	N		N	N	N	N		
						Swelling (svt)	N	N		N	N	N	N		
						Pain at the injection site	N	N		N	N	N	N		
			C4591001 1002 10021005	1	04MAY2020	Redness (svt)	N	N		N	N	N	N		
						Swelling (svt)	N	N		N	N	N	N		
						Pain at the injection site	N	N		N	N	N	N		
				2	26MAY2020	Redness (svt)	N	N	N	N	N		N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N		N		
						Pain at the injection site	N	N	N	N	N		N		
			C4591001 1002 10021008	1	06MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	26MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1002 10021018	1	11MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	02JUN2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			
						Pain at the injection site	N	N	N	N	N	N			
			C4591001 1002 10021021	1	13MAY2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	02JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1002 10021022	1	13MAY2020	Redness (cu)	1								
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	02JUN2020	Pain at the injection site	N	N	N	N	N	N	N		
						Redness (svt)		N	N	N	N	N	N		
						Swelling (svt)		N	N	N	N	N	N		
						Pain at the injection site		Mild	Mild	Mild	Mild	Mild	Mild	14JUN2020	12
			C4591001 1002 10021083	1	01JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)	1		2	2	1	1	1		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	21JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	21JUL2020	1

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Vaccine Group	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d		
							1	2	3	4	5	6	7				
BNT162b1	65-85	10 µg	C4591001 1001 10011037	1	11JUN2020	Redness (cu)		1									
						Redness (svt)	N	N		N	N	N	N				
						Swelling (svt)	N	N		N	N	N	N				
				Pain at the injection site	N	Mild		Mild	N	N	N		14JUN2020	3			
				2	30JUN2020	Redness (svt)	N	N	N	N	N	N	N				
						Swelling (svt)	N	N	N	N	N	N	N				
	Pain at the injection site	N	Mild			Mild	Mild	N	N	N	03JUL2020	3					
	C4591001 1001 10011039	1	09JUN2020	Redness (svt)	N	N	N	N	N	N							
				Swelling (svt)	N	N	N	N	N	N							
				Pain at the injection site	Mild	N	N	N	N	N		09JUN2020	1				
		2	29JUN2020	Redness (svt)	N	N	N	N	N	N	N						
				Swelling (svt)	N	N	N	N	N	N	N						

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	Mild	Mild	N	N	N	N	01JUL2020	2
			C4591001 1001 10011040	1	11JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	Mild	N	N	15JUN2020	5
				2	02JUL2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			
						Pain at the injection site	Mild	Mod	Mild	Mild	Mild	N		06JUL2020	5
			C4591001 1001 10011041	1	11JUN2020	Redness (svt)	N	N	N		N	N	N		
						Swelling (svt)	N	N	N		N	N	N		
						Pain at the injection site	N	Mild	N		N	N	N	12JUN2020	1
				2	02JUL2020	Redness (svt)	N		N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N		N	N	N	N	N		
						Pain at the injection site	N		N	N	N	N	N		
			C4591001 1001 10011044	1	09JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	N	N	N	N	11JUN2020	3
				2	29JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mod	N	N	N	N	N	30JUN2020	2
			C4591001 1001 10011045	1	11JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	02JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	03JUL2020	1
			C4591001 1002 10021043	1	09JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1002 10021044	1	09JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	Mild	N	N	N	N	N	N	09JUN2020	1
				2	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	30JUN2020	1
			C4591001 1002 10021045	1	11JUN2020	Redness (cu)	3								
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	01JUL2020	1

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
C4591001 1002 10021049				1	11JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
C4591001 1002 10021052				1	11JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1002 10021053	1	11JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)	10							11JUN2020	1
						Swelling (svt)	Mild	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	12JUN2020	2
				2	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)	12							30JUN2020	1
						Swelling (svt)	Mod	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	01JUL2020	2
		20 µg	C4591001 1001 10011043	1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	18JUN2020	4
				2	08JUL2020	Redness (svt)	N	N	N		N	N			
						Swelling (svt)	N	N	N		N	N			
						Pain at the injection site	Mild	Mod	Mild		Mild	N		12JUL2020	5
			C4591001 1001 10011049	1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	16JUN2020	2
				2	06JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	07JUL2020	2
			C4591001 1001 10011050	1	17JUN2020	Redness (cu)	4	2							

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)		12	9	8				20JUN2020	3
						Swelling (svt)	N	Mod	Mild	Mild	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	18JUN2020	2
				2	07JUL2020	Redness (cu)	1								
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)	4	17	12	6	12			11JUL2020	4
						Swelling (svt)	N	Mod	Mod	Mild	Mod	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	08JUL2020	2
			C4591001 1001 10011052	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	18JUN2020	1
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1001 10011055	1 17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mild	Mild	N	N	N	N	N	18JUN2020	2
				2 08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mild	Mild	N	N	N	N	N	09JUL2020	2
			C4591001 1001 10011059	1 17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	Mild	N	N	N	N	N	18JUN2020	1

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	09JUL2020	1
			C4591001 1002 10021054	1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	16JUN2020	2
				2	07JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	10JUL2020	4
			C4591001 1002 10021060	1	15JUN2020	Redness (cu)	1								
						Redness (svt)	N	N		N	N	N	N		
						Swelling (svt)	N	N		N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	Mild	Mild		N	N	N	N	17JUN2020	3
				2	07JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1002 10021064	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	08JUL2020	Redness (svt)	N	N	N						
						Swelling (svt)	N	N	N						
						Pain at the injection site	N	Mild	N					09JUL2020	1
			C4591001 1002 10021067	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	18JUN2020	1
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1002 10021068	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	18JUN2020	2
				2	08JUL2020	Redness (cu)				12	14			12JUL2020	2
						Redness (svt)	N	N	N	Mod	Mod	N	N		
						Swelling (cu)				12	14			12JUL2020	2
						Swelling (svt)	N	N	N	Mod	Mod	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	Mild	Mild	Mild	18JUL2020	11

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
			C4591001 1002 10021071	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mod	N	N	N	N	N	18JUN2020	1
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	09JUL2020	1
		30 µg	C4591001 1001 10011046	1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mod	N	N	N	N	N	19JUN2020	2
				2	09JUL2020	Redness (svt)	N	N	N	N		N	N		
						Swelling (svt)	N	N	N	N		N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
					Pain at the injection site	N	Mild	N	N		N	N	10JUL2020	1
			1	16JUN2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (cu)	8	8	5					18JUN2020	3
					Swelling (svt)	Mild	Mild	Mild	N	N	N	N		
					Pain at the injection site	Mod	Mild	Mild	N	N	N	N	18JUN2020	3
			2	08JUL2020	Redness (cu)	3		2						
					Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mild	N	N	N	N	N	N	08JUL2020	1
			1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	19JUN2020	2
				2	09JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1001 10011061	1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	19JUN2020	2
				2	09JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	10JUL2020	2
			C4591001 1001 10011063	1	18JUN2020	Redness (svt)		N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)		N	N	N	N	N	N		
						Pain at the injection site		Mod	N	N	N	N	N	19JUN2020	1
				2	07JUL2020	Redness (cu)			2	3	3				
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	Mild	Mild	Mild	Mild	N	12JUL2020	6
			C4591001 1002 10021059	1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	07JUL2020	Redness (svt)	N	N	N	N	N		N		
						Swelling (svt)	N	N	N	N	N		N		
						Pain at the injection site	N	N	N	N	N		N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
C4591001 1002 10021062				1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	Mild	Mild	N	N	N	18JUN2020	3
				2	07JUL2020	Redness (cu)				18	13	11	14JUL2020	4	
						Redness (svt)	N	N	N	N	Mod	Mod	Mod		
						Swelling (cu)					18	15		12JUL2020	2
						Swelling (svt)	N	N	N	N	Mod	Mod	N		
									12JUL2020	6					
C4591001 1002 10021063				1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	15JUN2020	1
				2	07JUL2020	Redness (svt)	N	N	N	N	N	N			

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	08JUL2020	1
			C4591001 1002 10021069	1	18JUN2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (cu)	6	7	6	6	4			21JUN2020	4
						Swelling (svt)	Mild	Mild	Mild	Mild	N	N			
						Pain at the injection site	Mild	Mild	Mild	N	N	N		20JUN2020	3
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)	1	8	6					10JUL2020	2
						Swelling (svt)	N	Mild	Mild	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	09JUL2020	2
			C4591001 1002 10021074	1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	Mild	Mild	Mild	N	N	N	N	20JUN2020	3
				2	08JUL2020	Redness (svt)	N		N	N	N	N	N		
						Swelling (svt)	N		N	N	N	N	N		
						Pain at the injection site	N		N	N	N	N	N		
			C4591001 1002 10021075	1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	19JUN2020	2
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)	8	6	4					09JUL2020	2
						Swelling (svt)	Mild	Mild	N	N	N	N	N		
						Pain at the injection site	Mod	Mild	Mild	N	N	N	N	10JUL2020	3

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
Placebo	65-85	Placebo	C4591001 1002 10021077	1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	19JUN2020	1
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			
						Pain at the injection site	Mod	N	N	N	N	N	08JUL2020	1	
Placebo	65-85	Placebo	C4591001 1001 10011042	1	11JUN2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			
						Pain at the injection site	N	N	N	N	N	N			
				2	30JUN2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1001 10011053	1	16JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	09JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1001 10011057	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	17JUN2020	1
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1001 10011064	1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	07JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1002 10021042	1	09JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	30JUN2020	Redness (svt)	N	N	N		N	N	N		
						Swelling (svt)	N	N	N		N	N	N		
						Pain at the injection site	N	N	N		N	N	N		
			C4591001 1002 10021047	1	11JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1002 10021050	1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	07JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1002 10021072	1	18JUN2020	Redness (svt)	N	N	N	N		N	N		
						Swelling (svt)	N	N	N	N		N	N		
						Pain at the injection site	N	N	N	N		N	N		
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1002 10021073	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
							1	2	3	4	5	6	7			
BNT162b2	18-55	10 µg	C4591001 1003 10031018	1	09JUN2020	Swelling (svt)	N	N	N	N	N	N	N			
						Pain at the injection site	N	N	N	N	N	N	N			
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N				
						Swelling (svt)	N	N	N	N	N	N				
				1	09JUN2020	Pain at the injection site	N	N	N	N	N	N				
						Redness (svt)	N	N	N	N	N	N	N			
			2	30JUN2020	C4591001 1003 10031018	Swelling (svt)	N	N	N	N	N	N	N			
						Pain at the injection site	N	Mild	N	N	N	N	N	10JUN2020	1	
					1	09JUN2020	Redness (svt)	N	N	N	N	N	N	N		
							Swelling (svt)	N	N	N	N	N	N	N		
					2	03JUL2020	Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	03JUL2020	4
							Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
C4591001 1003 10031019				1	11JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)		8						12JUN2020	1
						Swelling (svt)	N	Mild	N	N	N	N	N		
				2	02JUL2020	Pain at the injection site	Mod	Mod	Mild	N	N	N	N	13JUN2020	3
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
C4591001 1003 10031020				1	11JUN2020	Redness (svt)	N	N	N		N	N	N		
						Swelling (svt)	N	N	N		N	N	N		
						Pain at the injection site	Mild	Mild	N		N	N	N	12JUN2020	2
2	02JUL2020	Redness (svt)	N	N	N		N	N	N						
		Swelling (svt)	N	N	N		N	N	N						

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	Mild	N		N	N	N	03JUL2020	1
			C4591001 1003 10031021	1	09JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	12JUN2020	4
				2	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	N	N	N	N	02JUL2020	3
			C4591001 1003 10031022	1	11JUN2020	Redness (svt)	N	N		N	N	N	N		
						Swelling (svt)	N	N		N	N	N	N		
						Pain at the injection site	N	Mild		N	N	N	N	12JUN2020	1
				2	02JUL2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	N	N	N	N	N	N		
			1	11JUN2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (cu)	8							11JUN2020	1
					Swelling (svt)	Mild	N	N	N	N	N	N		
					Pain at the injection site	Mild	N	N	N	N	N	N	11JUN2020	1
			2	02JUL2020	Redness (svt)	N	N	N	N	N		N		
					Swelling (svt)	N	N	N	N	N		N		
					Pain at the injection site	Mild	N	N	N	N		N	02JUL2020	1
			1	11JUN2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	12JUN2020	2
				2	01JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071015	1	08JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	29JUN2020	Redness (svt)		N	N	N	N	N	N		
						Swelling (svt)		N	N	N	N	N	N		
						Pain at the injection site		N	N	N	N	N	N		
			C4591001 1007 10071016	1	10JUN2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	01JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	01JUL2020	1
			C4591001 1007 10071019	1	08JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	29JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
C4591001 1007 10071021				1	10JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	11JUN2020	2
				2	01JUL2020	Redness (svt)	N	N	N	N		N			
						Swelling (svt)	N	N	N	N		N			
						Pain at the injection site	Mild	N	N	N		N	01JUL2020	1	
C4591001 1007 10071022				1	10JUN2020	Redness (svt)	N	N	N	N		N	N		
						Swelling (svt)	N	N	N	N		N	N		
						Pain at the injection site	N	N	N	N		N	N		
				2	01JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
					Pain at the injection site	N	N	N	N	N	N	N		
		20 µg	C4591001 1003 10031026	1	17JUN2020	Redness (svt)	N	N	N		N	N		
					Swelling (svt)	N	N	N		N	N	N		
					Pain at the injection site	Mild	Mild	N		N	N	N	18JUN2020	2
				2	08JUL2020	Redness (svt)	N	N		N	N	N		
					Swelling (svt)	N	N		N	N	N	N		
					Pain at the injection site	Mild	Mild		N	N	N	N	09JUL2020	2
			C4591001 1003 10031027	1	15JUN2020	Redness (svt)	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mild	N	N	N	N	N	N	15JUN2020	1
				2	06JUL2020	Redness (svt)	N	N	N	N		N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N		N	N		
						Pain at the injection site	Mild	N	N	N		N	N	06JUL2020	1
			C4591001 1003 10031028	1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	06JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1003 10031030	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	18JUN2020	2

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	09JUL2020	2
			C4591001 1003 10031032	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mod	N	N	N	N	N	18JUN2020	2
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mod	N	N	N	N	N	09JUL2020	2
			C4591001 1003 10031038	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	09JUL2020	2
			C4591001 1007 10071017	1	15JUN2020	Redness (svt)	N	N	N		N	N	N		
						Swelling (svt)	N	N	N		N	N	N		
						Pain at the injection site	Mild	Mild	N		N	N	N	16JUN2020	2
				2	06JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)	3								
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mod	Mod	N	N	N	N	N	07JUL2020	2

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
						1	2	3	4	5	6	7			
C4591001 1007 10071023			1	17JUN2020	Redness (svt)	N	N	N	N	N		N			
					Swelling (svt)	N	N	N	N	N		N			
					Pain at the injection site	N	N	N	N	N		N			
			2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N			
					Swelling (svt)	N	N	N	N	N	N	N			
					Pain at the injection site	Mild	N	N	N	N	N	N	08JUL2020	1	
C4591001 1007 10071026			1	15JUN2020	Redness (svt)	N	N	N	N	N		N			
					Swelling (cu)	2	1								
					Swelling (svt)	N	N	N	N	N		N			
			2	06JUL2020	Pain at the injection site	Mild	Mild	N	N	N		N	16JUN2020	2	
					Redness (svt)	N	N	N	N	N	N	N			
					Swelling (cu)	2									

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mild	N	N	N	N	N	N	06JUL2020	1
			C4591001 1007 10071027	1 17JUN2020	Redness (svt)	N	N			N		N		
					Swelling (cu)		1							
					Swelling (svt)	N	N			N		N		
					Pain at the injection site	Mod	Mod			N		N	18JUN2020	2
				2 08JUL2020	Redness (svt)	N	N		N	N	N			
					Swelling (svt)	N	N		N	N	N			
					Pain at the injection site	Mild	Mod		N	N	N		09JUL2020	2
			C4591001 1007 10071029	1 17JUN2020	Redness (svt)	N	N		N	N	N	N		
					Swelling (svt)	N	N		N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	N		N	N	N	N		
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071040	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	18JUN2020	2
				2	08JUL2020	Redness (svt)	N	N	N	N		N	N		
						Swelling (svt)	N	N	N	N		N	N		
						Pain at the injection site	Mild	Mild	N	N		N	N	09JUL2020	2
		30 µg	C4591001 1003 10031057	1	24JUN2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mod	N	N	N	N	N	25JUN2020	2
				2	15JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	16JUL2020	2
			C4591001 1003 10031059	1	24JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	25JUN2020	2
				2	15JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	16JUL2020	2

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
C4591001 1003 10031061			1	22JUN2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mild	Mod	N	N	N	N	N	23JUN2020	2
			2	13JUL2020	Redness (svt)	N	N	N	N	N	N			
					Swelling (svt)	N	N	N	N	N	N			
					Pain at the injection site	N	Mild	N	N	N	N	14JUL2020	1	
C4591001 1003 10031065			1	24JUN2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	N	N	N	N	N	N		
			2	15JUL2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	Mild	N	N	N	N	N	16JUL2020	1
			C4591001 1003 10031066	1	22JUN2020	Redness (svt)	N	N	N	N	N		N		
						Swelling (svt)	N	N	N	N	N		N		
						Pain at the injection site	Mild	Mild	N	N	N		N	23JUN2020	2
				2	13JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	N	N	N	N	15JUL2020	3
			C4591001 1003 10031072	1	24JUN2020	Redness (cu)		8	6					26JUN2020	2
						Redness (svt)	N	Mild	Mild	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	27JUN2020	4

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
			2	16JUL2020	Redness (svt)	N	N	N	N		N	N		
					Swelling (svt)	N	N	N	N		N	N		
					Pain at the injection site	Mild	Mild	Mild	N		N	N	18JUL2020	3
		C4591001 1007 10071046	1	22JUN2020	Redness (svt)	N	N	N		N	N	N		
					Swelling (svt)	N	N	N		N	N	N		
					Pain at the injection site	Mild	Mild	N		N	N	N	23JUN2020	2
			2	15JUL2020	Redness (svt)	N	N	N	N	N				
					Swelling (svt)	N	N	N	N	N				
					Pain at the injection site	N	N	N	N	N				
		C4591001 1007 10071050	1	22JUN2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	Mild	N	N	N	N	N	23JUN2020	1
				2	13JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071058	1	24JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	25JUN2020	2
				2	15JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	N	N	N	N	17JUL2020	3
			C4591001 1007 10071063	1	24JUN2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
				2	15JUL2020	Pain at the injection site	Mild	Mild	Mild	N	N	N	N	26JUN2020	3
				2	15JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mod	N	N	N	N	N	16JUL2020	1
			C4591001 1007 10071064	1	24JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	25JUN2020	2
				2	15JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	15JUL2020	1

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
			C4591001 1007 10071066	1	24JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	25JUN2020	1
				2	15JUL2020	Redness (svt)	N	N	N		N	N			
						Swelling (svt)	N	N	N		N	N			
						Pain at the injection site	N	Mild	N		N	N	16JUL2020	1	
Placebo	18-55	Placebo	C4591001 1003 10031016	1	09JUN2020	Redness (svt)	N	N	N		N		N		
						Swelling (svt)	N	N	N		N		N		
						Pain at the injection site	N	N	N		N		N		
				2	30JUN2020	Redness (svt)	N	N	N	N		N	N		
						Swelling (svt)	N	N	N	N		N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	Mild	N	N		N	N	01JUL2020	1
			C4591001 1003 10031017	1	11JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	02JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1003 10031029	1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	06JUL2020	Redness (cu)	1								

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
					Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mild	N	N	N	N	N	N	06JUL2020	1
			C4591001 1003 10031034	1 17JUN2020	Redness (svt)		N	N	N	N	N	N		
					Swelling (svt)		N	N	N	N	N	N		
					Pain at the injection site		N	N	N	N	N	N		
				2 08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1003 10031050	1 22JUN2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	13JUL2020	Redness (svt)	N		N		N	N	N		
						Swelling (svt)	N		N		N	N	N		
						Pain at the injection site	N		N		N	N	N		
			C4591001 1003 10031070	1	24JUN2020	Redness (svt)	N		N	N	N	N	N		
						Swelling (svt)	N		N	N	N	N	N		
						Pain at the injection site	N		N	N	N	N	N		
				2	15JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071020	1	10JUN2020	Redness (svt)	N		N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N		N	N	N	N	N		
						Pain at the injection site	N		N	N	N	N	N		
				2	01JUL2020	Redness (cu)		2	1						
						Redness (svt)	N	N	N		N	N	N		
						Swelling (svt)	N	N	N		N	N	N		
						Pain at the injection site	N	N	N		N	N	N		
			C4591001 1007 10071025	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
						1	2	3	4	5	6	7			
BNT162b2	65-85	10 µg	C4591001 1007 10071065	1	24JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1003 10031076	2	15JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1003 10031076	1	29JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
C4591001 1003 10031076	2	20JUL2020	Redness (svt)	N	N	N	N	N	N	N					
			Swelling (svt)	N	N	N	N	N	N	N					

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	Mild	Mod	N	N	N	N	N	21JUL2020	2
			C4591001 1003 10031077	1	01JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	22JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1003 10031078	1	01JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	22JUL2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mild	Mild	Mild	N	N	N	N	24JUL2020	3
		C4591001 1003 10031079	1	01JUL2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	N	N	N	N	N	N		
			2	22JUL2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	N	N	N	N	N	N		
		C4591001 1003 10031080	1	29JUN2020	Redness (svt)	N	N		N	N	N	N		
					Swelling (svt)	N	N		N	N	N	N		
					Pain at the injection site	Mild	Mild		N	N	N	N	30JUN2020	2

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	20JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	21JUL2020	2
			C4591001 1003 10031087	1	01JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	01JUL2020	1
				2	22JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071051	1	29JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	20JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071057	1	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	22JUL2020	Redness (svt)	N	N	N	N	N		N		
						Swelling (svt)	N	N	N	N	N		N		
						Pain at the injection site	N	N	N	N	N		N		
			C4591001 1007 10071071	1	29JUN2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	29JUN2020	1
				2	20JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071073	1	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	Mild	N	N	N	N	02JUL2020	2
				2	22JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	Mild	N	N	N	N	24JUL2020	2

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
			C4591001 1007 10071074	1	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	20JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071077	1	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	22JUL2020	Redness (svt)		N	N	N	N	N	N		
						Swelling (svt)		N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
					Pain at the injection site		N	N	N	N	N	N		
		20 µg	C4591001 1003 10031031	1	15JUN2020	Redness (svt)	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	Mild	N	N	N	N	N	16JUN2020	1
				2	06JUL2020	Redness (svt)	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	Mild	N	N	N	N	N	07JUL2020	1
			C4591001 1003 10031035	1	15JUN2020	Redness (svt)	N	N		N	N	N		
					Swelling (svt)	N	N		N	N	N	N		
					Pain at the injection site	N	N		N	N	N	N		
				2	06JUL2020	Redness (svt)	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	Mild	Mild	N	N	N	09JUL2020	3
			C4591001 1003 10031053	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	18JUN2020	1
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1003 10031054	1	17JUN2020	Redness (svt)		N		N	N	N	N		
						Swelling (svt)		N		N	N	N	N		
						Pain at the injection site		N		N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
			2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	N	N	N	N	N	N		
		C4591001 1003 10031055	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mild	Mild	N	N	N	N	N	18JUN2020	2
			2	06JUL2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	Mild	N	N	N	N	N	07JUL2020	1
		C4591001 1003 10031063	1	17JUN2020	Redness (cu)		1							
					Redness (svt)	N	N	N	N	N	N	N		
					Swelling (cu)		1							

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	18JUN2020	1
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071031	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	09JUL2020	2

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
			C4591001 1007 10071032	1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	06JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071035	1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	06JUL2020	Redness (svt)		N	N	N	N	N	N		
						Swelling (svt)		N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site		N	N	N	N	N	N		
			C4591001 1007 10071038	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	18JUN2020	1
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	08JUL2020	1
			C4591001 1007 10071039	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	18JUN2020	1
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	Mild	N	N	N	N	N	09JUL2020	1
			C4591001 1007 10071052	1 17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	N	Mild	Mild	N	N	N	N	19JUN2020	2
				2 08JUL2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (cu)		3	3						
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mild	Mild	Mild	Mild	Mild	N	N	12JUL2020	5
		30 µg	C4591001 1003 10031037	1 16JUN2020	Redness (svt)	N	N		N	N	N	N		
					Swelling (svt)	N	N		N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	07JUL2020	Pain at the injection site	N	N		N	N	N	N		
				2	07JUL2020	Redness (svt)	N	N	N	N	N				
				2	07JUL2020	Swelling (svt)	N	N	N	N	N				
				1	16JUN2020	Pain at the injection site	N	Mild	N	N	N		08JUL2020	1	
			C4591001 1003 10031047	1	16JUN2020	Redness (svt)	N	N	N	N	N	N			
				1	16JUN2020	Swelling (svt)	N	N	N	N	N	N			
				2	07JUL2020	Pain at the injection site	Mild	N	N	N	N	N	16JUN2020	1	
				2	07JUL2020	Redness (svt)	N	N	N	N	N	N			
				2	07JUL2020	Swelling (svt)	N	N	N	N	N	N			
				1	18JUN2020	Pain at the injection site	Mod	N	N	N	N	N	07JUL2020	1	
			C4591001 1003 10031051	1	18JUN2020	Redness (svt)	N	N	N	N	N	N			

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	19JUN2020	1
				2	09JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mod	Mild	N	N	N	N	11JUL2020	3
			C4591001 1003 10031058	1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	19JUN2020	2
				2	09JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	10JUL2020	2

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate (Years)	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
							1	2	3	4	5	6	7			
			C4591001 1003 10031069	1	18JUN2020	Redness (cu)	1		1	1	1					
						Redness (svt)	N	N	N	N	N	N	N			
						Swelling (cu)	1									
						Swelling (svt)	N	N	N	N	N	N	N			
						Pain at the injection site	Mild	Mild	N	N	N	N	N	19JUN2020	2	
				2	09JUL2020	Redness (cu)	1	1	1	1						
						Redness (svt)	N	N	N	N	N	N	N			
						Swelling (cu)	1	1	1	1						
						Swelling (svt)	N	N	N	N	N	N	N			
						Pain at the injection site	Mild	Mild	N	N	N	N	N	10JUL2020	2	
			C4591001 1007 10071034	1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N	N			

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	Mild	N	N	N	N	N	16JUN2020	1
				2	06JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071037	1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	06JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071043	1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	09JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	10JUL2020	1
			C4591001 1007 10071044	1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	18JUN2020	1
				2	09JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
C4591001 1007 10071045				1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	19JUN2020	1
				2	09JUL2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			
						Pain at the injection site	N	N	N	N	N	N			
C4591001 1007 10071049				1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	Mild	N	N	N	N	N	19JUN2020	1
				2	09JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart															
Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	Mild	N	N	N	N	N	10JUL2020	1
			C4591001 1007 10071053	1	18JUN2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			
						Pain at the injection site	N	Mild	N	N	N	N		19JUN2020	1
				2	09JUL2020	Redness (svt)	N	N	N		N	N	N		
						Swelling (svt)	N	N	N		N	N	N		
						Pain at the injection site	N	Mild	N		N	N	N	10JUL2020	1
Placebo	65-85	Placebo	C4591001 1003 10031036	1	15JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	06JUL2020	Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1003 10031043	1	16JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	07JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1003 10031046	1	18JUN2020	Redness (svt)	N	N	N	N		N	N		
						Swelling (svt)	N	N	N	N		N	N		
						Pain at the injection site	N	N	N	N		N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
				2	09JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1003 10031056	1	18JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	09JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1003 10031067	1	17JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	08JUL2020	Redness (cu)			1						
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)	1								
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1003 10031083	1	01JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	22JUL2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	N	N	N	N	N	N	22JUL2020	1

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
C4591001 1007 10071042				1	17JUN2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			
						Pain at the injection site	N	N	N	N	N	N			
				2	08JUL2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			
						Pain at the injection site	N	N	N	N	N	N			
C4591001 1007 10071056				1	29JUN2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			
						Pain at the injection site	N	N	N	N	N	N			
				2	20JUL2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N			

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate (Years)	Age Group	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	N	N	N	N	N	N	N		
			C4591001 1007 10071075	1	30JUN2020	Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
				2	22JUL2020	Redness (svt)	N	N	N		N	N	N		
						Swelling (svt)	N	N	N		N	N	N		
						Pain at the injection site	N	N	N		N	N	N		

Abbreviations: cu = caliper units; Dur = duration; Mod = moderate; N = none; Sev = severe; svt = severity.

Note: For a given day, if no data are displayed for all local reactions, it indicates that the subject did not make any electronic diary (e-diary) entries and/or no data were transmitted.

a. Relative Day (Rel Day) = date of reaction - date of last vaccination + 1.

b. The maximum measurable size for redness and swelling in the electronic diary (e-diary) was 21 caliper units. Redness and swelling exceeding 21 caliper units are reported as >21. Study sites recorded injection site redness or swelling in centimeters. These were converted to caliper units (1 caliper unit = 0.5 centimeters).

c. Stop date is the date the reaction was last reported.

d. Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered which was used for the duration calculation.

16.2.7.2.1 Listing of Local Reactions – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (00:51) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adce_1004_lr_p1															

16.2.7.2.1.1 Listing of Local Reactions Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
							1	2	3	4	5	6	7			
BNT162b1	18-55	100 µg	C4591001 1001 10011026	1	18MAY2020	Redness (svt)	N	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N	N			
						Pain at the injection site	Mild	Mild	N	N	N	N	N	19MAY2020	2	
			C4591001 1001 10011028	1	20MAY2020	Redness (svt)	N	N	N	N	N	N	N			
						Swelling (svt)	N	N	N	N	N	N	N			
						Pain at the injection site	Mod	Mod	Mod	Mild	N	N	N	23MAY2020	4	
			C4591001 1001 10011030	1	20MAY2020	Redness (cu)			10	6	4				23MAY2020	2
						Redness (svt)	N	N	Mild	Mild	N	N	N			
						Swelling (cu)			16	6				23MAY2020	2	
Swelling (svt)	N	N				Mod	Mild	N	N	N						
Pain at the injection site	Mild	N				Mild	Mild	N	N	N	23MAY2020	4				

16.2.7.2.1.1 Listing of Local Reactions Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
			C4591001 1001 10011032	1	20MAY2020	Redness (cu)				13		13		25MAY2020	3
						Redness (svt)	N	N	N	Mod		Mod	N		
						Swelling (cu)		15	13	11				23MAY2020	3
						Swelling (svt)	N	Mod	Mod	Mod		N	N		
						Pain at the injection site	Mild	Mod	Mild	Mild		N	N	23MAY2020	4
			C4591001 1001 10011034	1	20MAY2020	Redness (cu)		5		7	7			24MAY2020	4
						Redness (svt)	N	Mild	N	Mild	Mild	N	N		
						Swelling (cu)		7	9	7				23MAY2020	3
						Swelling (svt)	N	Mild	Mild	Mild	N	N	N		
						Pain at the injection site	Sev	Mod	Mild	Mild	Mild	N	N	24MAY2020	5
			C4591001 1002 10021023	1	18MAY2020	Redness (cu)			6	16		16		23MAY2020	4

16.2.7.2.1.1 Listing of Local Reactions Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
						1	2	3	4	5	6	7		
					Redness (svt)	N	N	Mild	Mod	N	Mod	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mod	Mod	Mild	Mild	Mild	Mild	N	23MAY2020	6
			C4591001 1002 10021024	1 18MAY2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mod	Mod	Mild	N	N	N	N	20MAY2020	3
			C4591001 1002 10021027	1 18MAY2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		
					Pain at the injection site	Mod	Mod	Mild	N	N	N	N	20MAY2020	3
			C4591001 1002 10021034	1 21MAY2020	Redness (svt)	N	N	N	N	N	N	N		
					Swelling (svt)	N	N	N	N	N	N	N		

16.2.7.2.1.1 Listing of Local Reactions Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	24MAY2020	4
			C4591001 1002 10021035	1	21MAY2020	Redness (cu)			2						
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (cu)	5							21MAY2020	1
						Swelling (svt)	Mild	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	Mild	Mild	N	N	N	24MAY2020	4
			C4591001 1002 10021036	1	21MAY2020	Redness (svt)	N	N	N	N	N	N			
						Swelling (cu)		5	5	3				23MAY2020	2
						Swelling (svt)	N	Mild	Mild	N	N	N			
						Pain at the injection site	Mod	Mod	Mild	Mild	N	N		24MAY2020	4
			C4591001 1002 10021038	1	21MAY2020	Redness (svt)	N	N	N		N	N	N		

16.2.7.2.1.1 Listing of Local Reactions Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
Placebo	18-55	Placebo	C4591001 1001 10011013	1	18MAY2020	Swelling (svt)	N	N	N		N	N	N		
						Pain at the injection site	Mild	Mod	N		N	N	N	22MAY2020	2
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
						Redness (svt)	N	N	N	N	N	N	N		
			C4591001 1002 10021041	1	20MAY2020	Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	Mild	Mild	N	N	N	N	N	21MAY2020	2
						Redness (svt)	N	N	N	N	N	N	N		
						Swelling (svt)	N	N	N	N	N	N	N		
						Pain at the injection site	N	N	N	N	N	N	N		
						Redness (svt)	N	N	N	N	N	N	N		

16.2.7.2.1.1 Listing of Local Reactions Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
							1	2	3	4	5	6	7		
						Pain at the injection site	Mild	N	N	N	N	N	N	21MAY2020	1

Abbreviations: cu = caliper units; Dur = duration; Mod = moderate; N = none; Sev = severe; svt = severity.

Note: For a given day, if no data are displayed for all local reactions, it indicates that the subject did not make any electronic diary (e-diary) entries and/or no data were transmitted.

- Relative Day (Rel Day) = date of reaction - date of last vaccination + 1.
- The maximum measurable size for redness and swelling in the electronic diary (e-diary) was 21 caliper units. Redness and swelling exceeding 21 caliper units are reported as >21. Study sites recorded injection site redness or swelling in centimeters. These were converted to caliper units (1 caliper unit = 0.5 centimeters).
- Stop date is the date the reaction was last reported.
- Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered which was used for the duration calculation.

PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 18SEP2020 (19:40)

(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adce_1004_lr_100_p1

16.2.7.2.2 Listing of Severe and Grade 4 Local Reactions – Phase 2

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
18-55	C4591001 1127 11271014	2	19AUG2020	Pain at the injection site		Sev	Mod	Mild	Mild	Mild	N	24AUG2020	5
56-85	C4591001 1001 10011084	1	28JUL2020	Pain at the injection site	Mod	Sev	N	N	N	N	N	29JUL2020	2
	C4591001 1109 11091008	2	18AUG2020	Redness (cu)			15		21			22AUG2020	3
				Redness (svt)	N	N	Mod	N	Sev	N	N		

Abbreviations: cu = caliper units; Dur = duration; Mod = moderate; N = none; Sev = severe; svt = severity.

a. Relative Day (Rel Day) = date of reaction - date of last vaccination + 1.

b. The maximum measurable size for redness and swelling in the electronic diary (e-diary) was 21 caliper units. Redness and swelling exceeding 21 caliper units are reported as >21. Study sites recorded injection site redness or swelling in centimeters. These were converted to caliper units (1 caliper unit = 0.5 centimeters).

c. Stop date is the date the reaction was last reported.

d. Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered which was used for the duration calculation.

PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 11SEP2020 (11:50)

(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adce_1004_sevlr_p2

16.2.7.2.4 Listing of Severe and Grade 4 Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
16-55	C4591001 1007 10071111	1	03AUG2020	Pain at the injection site	Mod	Sev	Mild	N		N	N	05AUG2020	3
	C4591001 1013 10131180	1	13AUG2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	Mild		19AUG2020	7
		2	03SEP2020	Redness (cu)	21							03SEP2020	1
				Redness (svt)	Sev	N							
	C4591001 1015 10151015	2	04SEP2020	Redness (cu)			18	21	21	14	13	10SEP2020	5
				Redness (svt)	N	N	Mod	Sev	Sev	Mod	Mod		
				Swelling (cu)			11	21				07SEP2020	2
				Swelling (svt)	N	N	Mod	Sev	N	N	N		
	C4591001 1015 10151030	1	15AUG2020	Pain at the injection site	Mild	Sev	Mild	Mild	N	N	N	18AUG2020	4
		2	04SEP2020	Pain at the injection site	Mod	Sev		Mild	N	Mild			
	C4591001 1016 10161087	1	10AUG2020	Swelling (cu)	9	15	>21	19			9	21AUG2020	12
				Swelling (svt)	Mild	Mod	Sev	Mod		N	Mild		
				Pain at the injection site	Mod	Mod	Sev	Mod		N	N	13AUG2020	4
	C4591001 1016 10161106	1	12AUG2020	Pain at the injection site	Mild	Sev	Mild	Mild	Mild	N		16AUG2020	5
	C4591001 1056 10561108	1	01SEP2020	Swelling (cu)		11	20	21				05SEP2020	4
				Swelling (svt)		Mod	Mod	Sev					
	C4591001 1077 10771013	2	31AUG2020	Redness (cu)				>21				03SEP2020	1
				Redness (svt)	N	N	N	Sev		N	N		

16.2.7.2.4 Listing of Severe and Grade 4 Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
				Swelling (cu)		20	20	>21		18		05SEP2020	5
				Swelling (svt)	N	Mod	Mod	Sev		Mod	N		
	C4591001 1083 10831020	2	24AUG2020	Pain at the injection site	Mild	Sev	N	N		N	N	25AUG2020	2
	C4591001 1089 10891025	2	20AUG2020	Pain at the injection site	Mild	Sev	Mod	Mild	Mild		N	24AUG2020	5
	C4591001 1089 10891107	2	02SEP2020	Redness (cu)		18	21					04SEP2020	2
				Redness (svt)	N	Mod	Sev		N	N	N		
				Swelling (cu)		18	21					04SEP2020	2
				Swelling (svt)	N	Mod	Sev		N	N	N		
	C4591001 1089 10891131	1	17AUG2020	Swelling (cu)	21							17AUG2020	1
				Swelling (svt)	Sev	N	N	N	N	N	N		
	C4591001 1090 10901043	2	24AUG2020	Pain at the injection site	Sev	Sev	Mild	N		N	Mild		
	C4591001 1091 10911046	2	25AUG2020	Redness (cu)		16	21	21				28AUG2020	3
				Redness (svt)	N	Mod	Sev	Sev	N	N	N		
	C4591001 1109 11091102	2	21AUG2020	Pain at the injection site	Sev	Mod	N	N	N	N	N	22AUG2020	2
	C4591001 1109 11091204	1	11AUG2020	Pain at the injection site	Mod	Sev	Mild	N	N	N	N	13AUG2020	3
	C4591001 1120 11201130	2	03SEP2020	Pain at the injection site	Sev	Mod	Mild	Mild	Mild		N	07SEP2020	5
	C4591001 1120 11201238	1	21AUG2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	22AUG2020	2

16.2.7.2.4 Listing of Severe and Grade 4 Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
					1	2	3	4	5	6	7			
	C4591001 1124 11241039	2	03SEP2020	Swelling (cu)		21	1						04SEP2020	1
				Swelling (svt)	N	Sev	N	N	N	N	N			
				Pain at the injection site	N	Sev	Mod	N	N	N	N		05SEP2020	2
	C4591001 1127 11271014	2	19AUG2020	Pain at the injection site		Sev	Mod	Mild	Mild	Mild	N		24AUG2020	5
	C4591001 1127 11271022	1	30JUL2020	Pain at the injection site		Sev	Mod		Mild	N	N		03AUG2020	4
	C4591001 1127 11271032	1	31JUL2020	Pain at the injection site	Mod	Sev	Mild	Mild	Mild	N	N		04AUG2020	5
	C4591001 1129 11291045	2	25AUG2020	Redness (cu)		7	21						27AUG2020	2
				Redness (svt)	N	Mild	Sev		N	N				
	C4591001 1135 11351060	2	28AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N		30AUG2020	3
	C4591001 1135 11351105	2	31AUG2020	Pain at the injection site	N	Sev	Mod	Mild	Mild	N	N		04SEP2020	4
	C4591001 1140 11401051	1	06AUG2020	Pain at the injection site	Sev	Mod	N	N	N	N	N		07AUG2020	2
	C4591001 1140 11401065	1	06AUG2020	Swelling (cu)		21	10	5					09AUG2020	3
				Swelling (svt)	N	Sev	Mild	Mild	N		N			
				Pain at the injection site	Mild	Sev	Mod	Mild	Mild		N		10AUG2020	5
		2	28AUG2020	Pain at the injection site	N	Sev	Mod	Mod	Mild	Mild			03SEP2020	6
	C4591001 1147 11471019	2	24AUG2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	N	N		27AUG2020	4

16.2.7.2.4 Listing of Severe and Grade 4 Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
	C4591001 1152 11521076	2	03SEP2020	Pain at the injection site	Mild	Sev	Mild	Mild	Mild	N	N	07SEP2020	5
	C4591001 1162 11621019	1	03AUG2020	Pain at the injection site	N	Sev	N	N	N		N	04AUG2020	1
	C4591001 1163 11631036	2	25AUG2020	Redness (cu)				21				03SEP2020	7
				Redness (svt)		N		Sev					
				Pain at the injection site		N		Sev				03SEP2020	7
	C4591001 1226 12261008	2	24AUG2020	Pain at the injection site		Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1226 12261011	1	05AUG2020	Pain at the injection site	Sev	Mod	N	N	N	N		06AUG2020	2
	C4591001 1226 12261044	1	07AUG2020	Pain at the injection site	N		N	Sev	Mild	Mild	N	12AUG2020	3
	C4591001 1226 12261089	2	01SEP2020	Redness (cu)				21	21	12		05SEP2020	3
				Redness (svt)	N	N	Sev	Sev	Mod	N	N		
				Swelling (cu)				21	21			04SEP2020	2
				Swelling (svt)	N	N	Sev	Sev	N	N	N		
	C4591001 1226 12261096	1	11AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	Mild	N	16AUG2020	6
	C4591001 1226 12261140	1	12AUG2020	Pain at the injection site	N	Sev	N	N	N	N	N	13AUG2020	1
	C4591001 1229 12291001	2	14OCT2020	Pain at the injection site		Sev	Mod	N	N	N	N	16OCT2020	2
	C4591001 1229 12291002	1	22SEP2020	Pain at the injection site	N	Sev	N	N	N	N	N	23SEP2020	1

16.2.7.2.4 Listing of Severe and Grade 4 Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
					1	2	3	4	5	6	7			
	C4591001 1229 12291008	2	15OCT2020	Swelling (cu)	12	21							16OCT2020	2
				Swelling (svt)	Mod	Sev	N	N	N	N	N			
	C4591001 1229 12291024	1	28SEP2020	Redness (cu)	21								28SEP2020	1
				Redness (svt)	Sev	N	N	N	N	N	N			
				Swelling (cu)		21							29SEP2020	1
				Swelling (svt)	N	Sev	N	N	N	N	N			
	C4591001 1229 12291032	1	28SEP2020	Redness (cu)	21								28SEP2020	1
				Redness (svt)	Sev	N	N	N	N	N	N			
	C4591001 1229 12291047	1	29SEP2020	Pain at the injection site	Sev	Mild		N	N	N	N		30SEP2020	2
	C4591001 1229 12291082	1	01OCT2020	Redness (cu)	21								01OCT2020	1
				Redness (svt)	Sev	N		N	N	N				
	C4591001 1229 12291104	1	05OCT2020	Pain at the injection site	Sev	Sev	Mod	Mod	Mild					
	C4591001 1229 12291105	2	26OCT2020	Pain at the injection site	Mod	Sev	N	Mod	N	N	N		29OCT2020	4
	C4591001 1229 12291108	1	05OCT2020	Redness (cu)		21		21					08OCT2020	3
				Redness (svt)	N	Sev	N	Sev	N	N	N			
				Swelling (cu)				21					08OCT2020	1
				Swelling (svt)	N	N	N	Sev	N	N	N			
	C4591001 1229 12291109	1	05OCT2020	Redness (cu)		21							06OCT2020	1

16.2.7.2.4 Listing of Severe and Grade 4 Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
	C4591001 1229 12291114	1	06OCT2020	Redness (svt) Redness (cu)	N 21	Sev	N	N	N	N	N	06OCT2020	1
	C4591001 1229 12291124	1	06OCT2020	Redness (svt) Pain at the injection site	Sev Mod	N Sev	N Mild	N N	N	N	N	08OCT2020	3
	C4591001 1229 12291127	2	27OCT2020	Redness (cu)		21							
	C4591001 1230 12301018	1	24SEP2020	Redness (svt) Pain at the injection site	Sev	Sev	Mild	N	N	N	N	26SEP2020	3
	C4591001 1230 12301021	1	24SEP2020	Redness (cu)	21							24SEP2020	1
	C4591001 1230 12301072	1	29SEP2020	Redness (svt) Redness (cu)	Sev 21	N	N		N	N	N	29SEP2020	1
	C4591001 1230 12301133	1	05OCT2020	Redness (svt) Redness (cu)	Sev	N	N	N	N	N	N	07OCT2020	1
	C4591001 1231 12311018	2	27AUG2020	Redness (svt) Pain at the injection site	N	N	Sev	N	N	N	N	31AUG2020	4
	C4591001 1231 12311055	1	11AUG2020	Pain at the injection site	Mild	Sev	Mod	Mild	Mild	Mild	Mild	17AUG2020	7
	C4591001 1231 12311162	1	13AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	15AUG2020	3
	C4591001 1231 12311231	2	03SEP2020	Pain at the injection site	Mod	Sev	Mod	Mod	Mod	Mild	N	08SEP2020	6

16.2.7.2.4 Listing of Severe and Grade 4 Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
					1	2	3	4	5	6	7			
	C4591001 1231 12311295	2	03SEP2020	Pain at the injection site	N	Mild	Sev	Mod	Mild	Mild			10SEP2020	7
	C4591001 1231 12311304	2	04SEP2020	Pain at the injection site		Sev	N	Mild	N	N	N		07SEP2020	3
	C4591001 1231 12311386	1	15AUG2020	Pain at the injection site	Mod	Sev	N	N	N	N	N		16AUG2020	2
	C4591001 1231 12311494	2	06SEP2020	Pain at the injection site	Sev	Mod	Mild	Mild	N	N			09SEP2020	4
	C4591001 1231 12311513	2	08SEP2020	Pain at the injection site	N	Sev	Mild	N	N	N	N		10SEP2020	2
	C4591001 1232 12321010	2	02SEP2020	Pain at the injection site		Sev	N	Mild	N	N	N		05SEP2020	3
	C4591001 1246 12461025	1	28SEP2020	Pain at the injection site	Mod	Sev	Mild	N	N	N	N		30SEP2020	3
	C4591001 1246 12461055†	1	02OCT2020	Redness (cu)	21								02OCT2020	1
				Redness (svt)	Sev	N	N	N	N	N	N			
	C4591001 1247 12471033	2	15OCT2020	Pain at the injection site	N			Sev	Sev	N	N		19OCT2020	2
	C4591001 1247 12471071	1	28SEP2020	Swelling (cu)		21							29SEP2020	1
				Swelling (svt)	N	Sev	N	N	N	N	N			
	C4591001 1247 12471156	2	22OCT2020	Redness (cu)		21							23OCT2020	1
				Redness (svt)	N	Sev	N		N	N	N			
				Swelling (cu)		21							23OCT2020	1
				Swelling (svt)	N	Sev	N		N	N	N			

16.2.7.2.4 Listing of Severe and Grade 4 Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
>55	C4591001 1247 12471159	1	05OCT2020	Pain at the injection site	Sev	Mild	N	N		N	N	06OCT2020	2
	C4591001 1247 12471199	1	06OCT2020	Redness (cu)	21	21						07OCT2020	2
				Redness (svt)	Sev	Sev		N			N		
				Swelling (cu)	21							06OCT2020	1
				Swelling (svt)	Sev	N		N			N		
	C4591001 1001 10011084	1	28JUL2020	Pain at the injection site	Mod	Sev	N	N	N	N	N	29JUL2020	2
	C4591001 1055 10551017	1	10AUG2020	Pain at the injection site	Mild	Sev	N		N	N	N	11AUG2020	2
	C4591001 1085 10851059	2	02SEP2020	Redness (cu)		21	15	15				05SEP2020	3
				Redness (svt)	N	Sev	Mod	Mod	N	N	N		
				Swelling (cu)		21		15				05SEP2020	3
				Swelling (svt)	N	Sev	N	Mod	N	N	N		
	C4591001 1087 10871040	1	08AUG2020	Swelling (cu)		21	12	20				11AUG2020	3
				Swelling (svt)	N	Sev	Mod	Mod	N	N	N		
	C4591001 1090 10901155	2	31AUG2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	01SEP2020	2
C4591001 1090 10901158	2	31AUG2020	Pain at the injection site	Mod	Sev	Mod	Sev	Mod	Mod	Mod	15SEP2020	16	
C4591001 1091 10911024	2	24AUG2020	Redness (cu)		3	21	15	>21			28AUG2020	3	
			Redness (svt)	N	N	Sev	Mod	Sev	N	N			
C4591001 1109 11091008	2	18AUG2020	Redness (cu)			15		21			22AUG2020	3	

16.2.7.2.4 Listing of Severe and Grade 4 Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
				Redness (svt)	N	N	Mod	N	Sev	N	N		
	C4591001 1109 11091093	2	24AUG2020	Pain at the injection site	Mod	Sev	Mod		Mild	Mild			
	C4591001 1110 11101015	1	01AUG2020	Redness (cu)		21						02AUG2020	1
				Redness (svt)	N	Sev	N	N	N	N	N		
	C4591001 1123 11231012	2	19AUG2020	Pain at the injection site		Sev	Mod	Mod	N	N	N	22AUG2020	3
	C4591001 1124 11241031	2	03SEP2020	Redness (cu)			21	20	15			07SEP2020	3
				Redness (svt)	N	N	Sev	Mod	Mod	N	N		
	C4591001 1140 11401034	1	04AUG2020	Pain at the injection site	N	Sev	N	N	N	N		05AUG2020	1
	C4591001 1142 11421044	2	29AUG2020	Swelling (cu)			21	10				01SEP2020	2
				Swelling (svt)	N		Sev	Mild		N	N		
	C4591001 1142 11421093	2	04SEP2020	Redness (cu)				21	21	16	16	13SEP2020	7
				Redness (svt)		N	N	Sev	Sev	Mod	Mod		
	C4591001 1145 11451012	2	02SEP2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	04SEP2020	3
	C4591001 1146 11461025	2	03SEP2020	Pain at the injection site	Sev	Mod		N	N	N	N	04SEP2020	2
	C4591001 1224 12241016	2	02SEP2020	Redness (cu)		19	17	21	21	20	20	08SEP2020	6
				Redness (svt)	N	Mod	Mod	Sev	Sev	Mod	Mod		
	C4591001 1224 12241019	2	02SEP2020	Redness (cu)		6	21	21				05SEP2020	3

16.2.7.2.4 Listing of Severe and Grade 4 Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
				Redness (svt)	N	Mild	Sev	Sev	N	N	N		
	C4591001 1226 12261033	1	06AUG2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	07AUG2020	2
	C4591001 1226 12261149	1	13AUG2020	Redness (cu)		21	10					15AUG2020	2
	C4591001 1229 12291040	2	21OCT2020	Redness (svt) Swelling (cu)		Sev 20	Mild 21	N	N	N	N	23OCT2020	2
	C4591001 1229 12291056	2	21OCT2020	Swelling (svt) Swelling (cu)	N	Mod 21	Sev	N	N	N	N	22OCT2020	1
	C4591001 1229 12291067	1	30SEP2020	Swelling (svt) Redness (cu)	N	Sev 10	N	N	N	N	N	03OCT2020	3
	C4591001 1229 12291084	2	21OCT2020	Redness (svt) Redness (cu)	N	Mild	N	Sev		N	N	26OCT2020	1
	C4591001 1229 12291087	2	23OCT2020	Redness (svt) Pain at the injection site	Sev					Sev	N		
	C4591001 1229 12291087	1	02OCT2020	Redness (cu)			21					04OCT2020	1
	C4591001 1229 12291097	1	05OCT2020	Redness (svt) Swelling (cu)		N 21	Sev 21	N		N	N	04OCT2020	2
	C4591001 1229 12291097	1	05OCT2020	Swelling (svt) Redness (cu)		Sev	Sev	N		N	N	05OCT2020	1
	C4591001 1229 12291097	1	05OCT2020	Redness (cu)	21								
	C4591001 1229 12291097	1	05OCT2020	Redness (svt)	Sev	N	N	N	N	N	N		

16.2.7.2.4 Listing of Severe and Grade 4 Local Reactions – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d	
					1	2	3	4	5	6	7			
	C4591001 1246 12461056	2	23OCT2020	Redness (cu)		21	4						24OCT2020	1
				Redness (svt)	N	Sev	N	N	N	N	N	N		
	C4591001 1247 12471056	2	15OCT2020	Pain at the injection site	Mod	Sev	Mod	Mild	Mild	N	N		19OCT2020	5

Abbreviations: cu = caliper units; Dur = duration; Mod = moderate; N = none; Sev = severe; svt = severity.

Note: † = HIV-positive subject.

a. Relative Day (Rel Day) = date of reaction - date of last vaccination + 1.

b. The maximum measurable size for redness and swelling in the electronic diary (e-diary) was 21 caliper units. Redness and swelling exceeding 21 caliper units are reported as >21. Study sites recorded injection site redness or swelling in centimeters. These were converted to caliper units (1 caliper unit = 0.5 centimeters).

c. Stop date is the date the reaction was last reported.

d. Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered which was used for the duration calculation.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 18NOV2020 (02:59)

(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001 IA P3 2MPD2/adce 1004 sevlr p3

16.2.7.2.6 Listing of Severe and Grade 4 Local Reactions – Subjects Enrolled in Multiple Sites

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction ^b	Rel Day ^a							Stop Date ^c	Dur (Days) ^d
					1	2	3	4	5	6	7		
No subject meets the reporting criteria.													
<p>a. Relative Day (Rel Day) = date of reaction - date of last vaccination + 1.</p> <p>b. The maximum measurable size for redness and swelling in the electronic diary (e-diary) was 21 caliper units. Redness and swelling exceeding 21 caliper units are reported as >21. Study sites recorded injection site redness or swelling in centimeters. These were converted to caliper units (1 caliper unit = 0.5 centimeters).</p> <p>c. Stop date is the date the reaction was last reported.</p> <p>d. Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered which was used for the duration calculation.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (22:37) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_1004_sev1r_menrol_p3</p>													

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
BNT162b1	18-55	10 µg	C4591001 1001 10011004	1	04MAY2020	Oral temperature (°C)	37.2		36.6	36.1	36.6	36.6	36.1		
						Fatigue	Mild	N	Mild	Mild	N	N	08MAY2020	5	
						Headache	Mild	N	N	Mild	N	N	08MAY2020	5	
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			
						New or worsened joint pain	N	N	N	N	N	N			
Use of antipyretic or pain medication	No	No	No	No	No	No									
				2	26MAY2020	Oral temperature (°C)	36.7	37.3		36.4	36.2	36.2			
						Fatigue	Mild Mod			N	N	N	27MAY2020	2	

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	Mild			N	N	N	27MAY2020	1
						Chills	N	N			N	N	N		
						Vomiting	N	N			N	N	N		
						Diarrhea	N	N			N	N	N		
						New or worsened muscle pain	N	N			N	N	N		
						New or worsened joint pain	N	Mod			N	N	N	27MAY2020	1
						Use of antipyretic or pain medication	No	Yes			No	No	No	27MAY2020	1
			C4591001 1001 10011006	1	06MAY2020	Oral temperature (°C)	36.9		37.3	36.7	36.6	36.4	36.1		
						Fatigue	Mild		N	N	N	N	N	06MAY2020	1
						Headache	N		Mild	N	N	N	N	08MAY2020	1
						Chills	N		N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N		N	N	N	N	N		
						Diarrhea	N		N	N	N	Mild	N	11MAY2020	1
						New or worsened muscle pain	N		N	N	N	N	N		
						New or worsened joint pain	N		N	N	N	N	N		
						Use of antipyretic or pain medication	No		No	No	No	No	No		
				2	27MAY2020	Oral temperature (°C)		36.3		36.6	36.7	36.7			
						Fatigue		N		N	N	N			
						Headache		Mild		N	N	N		28MAY2020	1
						Chills		N		N	N	N			
						Vomiting		N		N	N	N			
						Diarrhea		N		N	N	N			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N		N	N	N				
						New or worsened joint pain	N		N	N	N				
						Use of antipyretic or pain medication	Yes		No	No	No		28MAY2020	1	
			C4591001 1001 10011007	1	06MAY2020	Oral temperature (°C)	36.5	36.9	36.5	36.3	36.5	36.6	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	28MAY2020	Oral temperature (°C)	36.7	37.2	36.9	36.4	37.4	36.4	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1001 10011008	1	06MAY2020	Oral temperature (°C)	37.1	37	37	36.5	36.2	35.9	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	Mild	N	N	N	N	N	07MAY2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	Mild	13MAY2020	2
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	07MAY2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	27MAY2020	Oral temperature (°C)	36.2	37.4	36.7		36.2	36.5	37		
						Fatigue	N	Mild	Mild		N	N	N	29MAY2020	2
						Headache	N	Mild	Mild		N	N	N	29MAY2020	2
						Chills	N	N	N		N	N	N		
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	N	N		N	N	N		
						New or worsened joint pain	N	Mild	N		N	N	N	28MAY2020	1
						Use of antipyretic or pain medication	No	No	No		No	No	No		
			C4591001 1001 10011009	1	06MAY2020	Oral temperature (°C)	36.2	38.3	38.9	36.7	36.1	36.2	36.2	08MAY2020	2
						Fatigue	N	Mod	N	Mild	N	N	N	09MAY2020	3

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	Mod	Mod	N	Mild	N	N	10MAY2020	4
						Chills	N	Mod	N	N	N	N	N	07MAY2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	Mild	N	N	N	N	N	07MAY2020	1
						Use of antipyretic or pain medication	No	Yes	Yes	No	No	No	No	08MAY2020	2
				2	27MAY2020	Oral temperature (°C)	36.7	38.5	37.2	36.1	36.1	36.1	36.1	28MAY2020	1
						Fatigue	N	Sev	Mild	N	N	N	N	29MAY2020	2
						Headache	N	Mod	Mild	N	N	N	N	29MAY2020	2
						Chills	N	Mod	N	N	N	N	N	28MAY2020	1
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mod	Mild	N	N	N	N	29MAY2020	2
						New or worsened joint pain	N	Mod	N	N	N	N	N	28MAY2020	1
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	28MAY2020	1
			C4591001 1002 10021003	1	04MAY2020	Oral temperature (°C)	36.8	36.8	36.8	36.3	36.8	36.2	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	26MAY2020	Oral temperature (°C)	37.1	37.7	36.6	37.2	37.1	36.5	36.6		
						Fatigue	N	Mod	N	N	N	N	N	27MAY2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	27MAY2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	Yes	Yes	No	No	No	No	No	27MAY2020	2
			C4591001 1002 10021004	1	04MAY2020	Oral temperature (°C)	36.8	36.8	36.6	36.8	36.6	36.6	37		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	26MAY2020	Oral temperature (°C)	36.7	37.3	36.7	36.8	36.8	37.3	37		
						Fatigue	N	Mild	N	N	N	N	N	27MAY2020	1
						Headache	N	Mild	N	Mild	N	N	N	29MAY2020	3
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	27MAY2020	1
						New or worsened joint pain	N	Mod	N	N	N	N	N	27MAY2020	1
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1002 10021007	1	06MAY2020	Oral temperature (°C)	36.6	37.1	36.7		36.3	36.7	36.3		
						Fatigue	N	N	N		N	N	N		
						Headache	N	N	N		Mild	N	N	10MAY2020	1
						Chills	N	N	N		N	N	N		
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	N	N		N	N	N		
						New or worsened joint pain	N	N	N		N	N	N		
						Use of antipyretic or pain medication	No	No	No		No	No	No		
				2	26MAY2020	Oral temperature (°C)	36.4	37.3	36.2	36.9	36.7	36.7	36.7		
						Fatigue	N	Mild	Mild	N	N	N	N	28MAY2020	2

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c	
							1	2	3	4	5	6	7			
						Headache	N	Mild	N	N	N	N	N	N	27MAY2020	1
						Chills	N	Mod	N	N	N	N	N	N	27MAY2020	1
						Vomiting	N	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No	No		
			C4591001 1002 10021009	1	06MAY2020	Oral temperature (°C)	36.7	36.4	36.4	36.5	36.3	36.4	36.7			
						Fatigue	N	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	Mild	N	N	N	N	N	N	06MAY2020	1
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	26MAY2020	Oral temperature (°C)	36.6	37.2	36.6	36.6	36.2	36.4	36.5		
						Fatigue	N	Mod	N	N	N	N	N	27MAY2020	1
						Headache	N	Mild	N	N	N	N	N	27MAY2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	27MAY2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1002 10021011	1	06MAY2020	Oral temperature (°C)	36.4	36.7	35.9	36.4	36.1	36.6	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	26MAY2020	Oral temperature (°C)	36.2	37	36.4	36.3	37	36.8	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	Mild	N	N	N	N	N	27MAY2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1002 10021012	1	05MAY2020	Oral temperature (°C)	36.7	36.2	36.9	35.9	36.1	36.2	36.2		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	26MAY2020	Oral temperature (°C)	35.9	37.8	36.7	35.9	36	36.2	36.2		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	Mod	N	N	Mod	N	N	30MAY2020	4
						Chills	N	Mod	N	N	N	N	N	27MAY2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	Yes	No	No	30MAY2020	4
			C4591001 1002 10021013	1	06MAY2020	Oral temperature (°C)	35.6	36.1	35.6	36.1	35.6	35.6	35.6		
						Fatigue	N	Mild	N	N	N	N	Mild	13MAY2020	7

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	07MAY2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	26MAY2020	Oral temperature (°C)	36.3	37.3	36.2	36.7	36.5	36.6	36.6		
						Fatigue	N	Mod	N	N	N	N	N	27MAY2020	1
						Headache	N	Mod	N	N	N	N	N	27MAY2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	27MAY2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	27MAY2020	1
		20 µg	C4591001 1001 10011067	1	01JUL2020	Oral temperature (°C)	36.6	36.7	36.5	36.7	36.3	36.7	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	Mild	N	N	N	N	03JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	22JUL2020	Oral temperature (°C)	36.3	37.9	36.7	36.4		36.7			
						Fatigue	Mild	N	N	N		N		22JUL2020	1
						Headache	N	Mild	N	N		N		23JUL2020	1
						Chills	N	N	N	N		N			
						Vomiting	N	N	N	N		N			
						Diarrhea	N	N	N	N		N			
						New or worsened muscle pain	N	Mild	N	N		N		23JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	Mild	N	N		N		23JUL2020	1
						Use of antipyretic or pain medication	No	Yes	No	No		No		23JUL2020	1
			C4591001 1001 10011068	1	29JUN2020	Oral temperature (°C)	36.5	37.4	36.5	36.8	36.7	36.8	36.8		
						Fatigue	N	Mild	N	N	N	N	N	30JUN2020	1
						Headache	N	Mild	Mild	N	N	N	N	01JUL2020	2
						Chills	N	Mild	N	N	N	N	N	30JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	30JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	30JUN2020	1
				2	20JUL2020	Oral temperature (°C)	37.1	38.6	36.9	37.5	37.1	37.4	36.9	21JUL2020	1
						Fatigue	Mild	Mild	N	Mild	N	N	Mild	27JUL2020	8
						Headache	N	Mod	N	N	N	N	Mild	27JUL2020	7
						Chills	N	Mild	N	N	N	N	N	21JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mod	Mild	N	N	N	N	22JUL2020	2
						New or worsened joint pain	N	Mild	Mild	N	N	N	N	22JUL2020	2
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	21JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1001 10011070	1	01JUL2020	Oral temperature (°C)	36.8	37	36.8	36.9	36.8	36.8	36.4		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	22JUL2020	Oral temperature (°C)	37	36.7	36.6	36.8	36.7	36.8	36.8		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1001 10011071	1	01JUL2020	Oral temperature (°C)	36.3	36.5	36.6	36.2	36.5		36.4		
						Fatigue	Mod	Mild	N	N	N		N	02JUL2020	2
						Headache	N	N	N	N	N		N		
						Chills	N	N	N	N	N		N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N		N		
						Diarrhea	N	N	N	N	N		N		
						New or worsened muscle pain	N	N	N	N	N		N		
						New or worsened joint pain	N	N	N	N	N		N		
						Use of antipyretic or pain medication	No	No	No	No	No		No		
				2	22JUL2020	Oral temperature (°C)	37.2	38.3	36.9	36.6	36.7	36.6	36.5	23JUL2020	1
						Fatigue	Mod	Sev	Mild	Mild	N	N	N	25JUL2020	4
						Headache	N	N	N	N	N	N	N		
						Chills	Mild	Mod	N	N	N	N	N	23JUL2020	2
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	Mild	N	N	N	N	N	23JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	Mod	Mod	N	N	N	N	N	23JUL2020	2
						New or worsened joint pain	N	Mild	N	N	N	N	N	23JUL2020	1
						Use of antipyretic or pain medication	No	Yes	Yes	No	No	No	No	24JUL2020	2
			C4591001 1001 10011076	1	01JUL2020	Oral temperature (°C)	36.3	37.1	36.8		36.1	36.4	37.1		
						Fatigue	N	Mod	Mod		N	N	N	03JUL2020	2
						Headache	N	Mild	Mild		N	N	N	03JUL2020	2
						Chills	N	Mod	N		N	N	N	02JUL2020	1
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	Mod	N		N	N	N	02JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	Mod	N		N	N	N	02JUL2020	1
						Use of antipyretic or pain medication	No	Yes	Yes		No	No	No	03JUL2020	2
				2	21JUL2020	Oral temperature (°C)	37.1	37.8	37.1		36.7	36.7	36.7		
						Fatigue	Mild	Mild	Mild		N	N	N	23JUL2020	3
						Headache	N	Mild	Mild		N	N	N	23JUL2020	2
						Chills	N	N	N		N	N	N		
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	Mild	Mod	N		N	N	N	22JUL2020	2
						New or worsened joint pain	Mod	Mod	N		N	N	N	22JUL2020	2

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Use of antipyretic or pain medication	No	Yes	No		No	No	No	22JUL2020	1
			C4591001 1002 10021079	29JUN2020	Oral temperature (°C)	36.3	36.9	36.6	36.7	36.5	36.5	36.8		
					Fatigue	N	N	N	N	N	N	N		
					Headache	N	Mild	N	N	N	N	N	30JUN2020	1
					Chills	N	N	N	N	N	N	N		
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	N	N	N	N	N	N		
					New or worsened joint pain	N	N	N	N	N	N	N		
					Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	21JUL2020	Oral temperature (°C)	36.6	37.9	36.7	36.8	36.4	36.3	36.5		
						Fatigue	N	Mod	Mod	N	N	N	N	23JUL2020	2
						Headache	N	Mod	Mild	N	N	N	N	23JUL2020	2
						Chills	N	Mod	Mild	N	N	N	N	23JUL2020	2
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mod	N	N	N	N	N	22JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	Yes	No	No	No	No	23JUL2020	2
			C4591001 1002 10021080	1	01JUL2020	Oral temperature (°C)	36.7	36.7	36.2	36.5	36.7	36.1	36.1		
						Fatigue	N	Mod	N	N	N	N	N	02JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	Mod	N	N	N	N	N	02JUL2020	1
						Chills	Mod	N	N	N	N	N	N	01JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	Mild	N	N	N	N	N	N	01JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	21JUL2020	Oral temperature (°C)	36.7	36.8	36.1	36	36.5	36.7			
						Fatigue	N	Mild	N	N	N	N		22JUL2020	1
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	No	No	No	No	No			
			C4591001 1002 10021081	1	01JUL2020	Oral temperature (°C)	36.6		36.3	36.2	36.7	36.7	36.1		
						Fatigue	Mild		N	N	N	N	N	01JUL2020	1
						Headache	N		N	N	N	N	N		
						Chills	N		N	N	N	N	N		
						Vomiting	N		N	N	N	N	N		
						Diarrhea	N		N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N		N	N	N	N	N		
						New or worsened joint pain	N		N	N	N	N	N		
						Use of antipyretic or pain medication	No		No	No	No	No	No		
				2	21JUL2020	Oral temperature (°C)	36.5	37	36.3		36.8		37.9		
						Fatigue	Mod	Mod	N		N		Mod	29JUL2020	9
						Headache	N	N	N		N		Mild	28JUL2020	2
						Chills	N	N	N		N		Mod	28JUL2020	2
						Vomiting	N	N	N		N		N		
						Diarrhea	N	N	N		N		N		
						New or worsened muscle pain	N	N	N		N		Mod	28JUL2020	2

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N		N		Mod	28JUL2020	2
						Use of antipyretic or pain medication	No	No	No		No		Yes	28JUL2020	2
			C4591001 1002 10021082	1	01JUL2020	Oral temperature (°C)	36.5	37.2	36.8	36.5	36.8	36.2	36.4		
						Fatigue	N	Mild	N	Mild	N	N	N	04JUL2020	3
						Headache	N	Mild	N	N	N	N	N	02JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	Yes	Yes	No	No	No	No	No	02JUL2020	2
				2	21JUL2020	Oral temperature (°C)	37	37.9	36.6	36.6	36.8	36.7	36.7		
						Fatigue	N	Mild	N	N	N	N	N	22JUL2020	1
						Headache	N	Mild	N	N	N	N	N	22JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	Mod	Mild	N	Mild	28JUL2020	5
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	Yes	Yes	No	Yes	No	No	No	24JUL2020	4

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1002 10021084	1	29JUN2020	Oral temperature (°C)	36.7	36.5	36.3	36.3	36.4	36.6	36		
						Fatigue	N	Mild	N	N	N	N	N	30JUN2020	1
						Headache	N	Mild	N	N	N	N	N	30JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	21JUL2020	Oral temperature (°C)	36.9	37.2	37		36.2	36	36		
						Fatigue	N	Mild	N		N	N	N	22JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	Mild	N		N	N	N	22JUL2020	1
						Chills	N	N	N		N	N	N		
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	N	N		N	N	N		
						New or worsened joint pain	N	N	N		N	N	N		
						Use of antipyretic or pain medication	No	Yes	No		No	No	No	22JUL2020	1
			C4591001 1002 10021085	1	29JUN2020	Oral temperature (°C)	36.5	36.7	36.3	37.1		36.5	36.8		
						Fatigue	N	N	N	N		N	N		
						Headache	N	N	N	N		N	N		
						Chills	N	N	N	N		N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N		N	N		
						Diarrhea	N	N	N	N		N	N		
						New or worsened muscle pain	N	N	N	N		N	N		
						New or worsened joint pain	N	N	N	N		N	N		
						Use of antipyretic or pain medication	No	No	No	No		No	No		
				2	21JUL2020	Oral temperature (°C)	36.4	37.2		36.4	36.6	36.7	37		
						Fatigue	N	N		N	N	N	N		
						Headache	N	Mild		N	N	N	N	22JUL2020	1
						Chills	N	Mild		N	N	N	N	22JUL2020	1
						Vomiting	N	N		N	N	N	N		
						Diarrhea	N	N		N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	Mild		N	Mild	N	N	25JUL2020	4
						New or worsened joint pain	N	Mild		N	N	N	N	22JUL2020	1
						Use of antipyretic or pain medication	No	No		No	No	No	No		
			C4591001 1002 10021087	1	01JUL2020	Oral temperature (°C)	35.9	36.8	35.6	36	36.1	36.1			
						Fatigue	N	Mild	N	N	N	N		02JUL2020	1
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			

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16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	No	No	No	No	No			
				2	21JUL2020	Oral temperature (°C)	36.1	36.2		36.5	36.1	36	36.3		
						Fatigue	N	Mod		N	N	N	N	22JUL2020	1
						Headache	N	N		N	N	N	N		
						Chills	N	Mod		N	N	N	N	22JUL2020	1
						Vomiting	N	N		N	N	N	N		
						Diarrhea	N	N		N	N	N	N		
						New or worsened muscle pain	N	Mod		N	N	N	N	22JUL2020	1
						New or worsened joint pain	N	N		N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	Yes		No	No	No	No	22JUL2020	1
		30 µg	C4591001 1001 10011011	1	11MAY2020	Oral temperature (°C)	36.7	37.6	36.7	36.8	36.8	36.8	37.2		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	01JUN2020	Oral temperature (°C)	37.4	38.7	37.6	36.5	36.8	36.7	36.5	02JUN2020	1
						Fatigue	N	Mod	N	N	N	N	N	02JUN2020	1
						Headache	N	Mild	N	N	N	N	N	02JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	Mild	Mod	N	N	N	N	N	02JUN2020	2
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	02JUN2020	1
			C4591001 1001 10011012	1	13MAY2020	Oral temperature (°C)	35.9	37	36.8	36.5	36.2	36.3	35.8		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	Mild	Mod	N	N	N	N	15MAY2020	2
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	Yes	No	No	No	No	15MAY2020	1
				2	03JUN2020	Oral temperature (°C)	36	38.6	38.4	36.2	36.5	36.8	36.8	05JUN2020	2
						Fatigue	N	Mod	N	N	N	N	N	04JUN2020	1
						Headache	N	Mod	Mod	N	N	N	N	05JUN2020	2
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	N	N	N	N	N	N		
					New or worsened joint pain	N	Mod	Mild	N	N	N	N	05JUN2020	2
					Use of antipyretic or pain medication	No	Yes	Yes	No	No	No	No	05JUN2020	2
			C4591001 1001 10011015	1 11MAY2020	Oral temperature (°C)	35.9	37.7	36.7	36.8	36.2	36.6			
					Fatigue	N	N	N	N	N	N			
					Headache	N	Mild	N	N	N	N		12MAY2020	1
					Chills	N	Mod	N	N	N	N		12MAY2020	1
					Vomiting	N	N	N	N	N	N			
					Diarrhea	N	Mod	N	N	N	N		12MAY2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N			
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	12MAY2020	1	
				2	01JUN2020	Oral temperature (°C)	36.5		38.3	36.3	36.4	36.4	36.5	03JUN2020	1
						Fatigue	N		N	Mild	Mild	N	N	05JUN2020	2
						Headache	N		Mod	Mod	Mild	N	N	05JUN2020	3
						Chills	N		N	N	N	N	N		
						Vomiting	N		N	N	N	N	N		
						Diarrhea	N		N	Mild	N	N	N	04JUN2020	1
						New or worsened muscle pain	N		N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N		N	N	N	N	N		
						Use of antipyretic or pain medication	No		Yes	Yes	No	No	No	04JUN2020	2
			C4591001 1001 10011017	1	13MAY2020	Oral temperature (°C)	36.7	37.8	36.7	36.5		36.5	36.4		
						Fatigue	N	Mild	Mild	N		N	N	15MAY2020	2
						Headache	N	N	N	N		N	N		
						Chills	N	Mild	N	N		N	N	14MAY2020	1
						Vomiting	N	N	N	N		N	N		
						Diarrhea	N	N	N	N		N	N		
						New or worsened muscle pain	N	N	N	N		N	N		
						New or worsened joint pain	N	N	N	N		N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No			
				2	03JUN2020	Oral temperature (°C)	37.3	38.7	37.7	37.2	36.3	36.3	36.6	04JUN2020	1
						Fatigue	Mod	Mod	N	N	N	N	N	04JUN2020	2
						Headache	N	Mild	N	N	N	N	N	04JUN2020	1
						Chills	N	Mod	N	N	N	N	N	04JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mod	N	N	N	N	N	04JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	Yes	Yes	No	No	No	06JUN2020	3

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1001 10011019	1	13MAY2020	Oral temperature (°C)	36.3	37.4	36.9	36.7	36.9	36.8	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	Mod	N	N	N	N	N	14MAY2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	03JUN2020	Oral temperature (°C)	37.1	38.6	37.6	36.8	36.6	36.3	36.6	04JUN2020	1
						Fatigue	N	Mod	N	N	N	N	N	04JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	Mild	Mild	N	N	N	N	05JUN2020	2
						Chills	N	Mild	N	N	N	N	N	04JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	04JUN2020	1
			C4591001 1001 10011020	1	13MAY2020	Oral temperature (°C)	36.7	37.1	36.7	36.6	36.5	36.5	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	Mild	N	N	N	N	N	14MAY2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	03JUN2020	Oral temperature (°C)	37	37.3	36.1	37	36.5	36.3	36.8		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	Mild	N	N	N	N	N	04JUN2020	1
						Chills	N	Mild	N	N	N	N	N	04JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	04JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1001 10011024	1	13MAY2020	Oral temperature (°C)	38.2	36.3	36	36.6	36.5	36.2	36.6	13MAY2020	1
						Fatigue	Mild	Mild	N	N	N	N	N	14MAY2020	2
						Headache	N	Mod	N	N	N	N	N	14MAY2020	1
						Chills	Mild	N	N	N	N	N	N	13MAY2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	03JUN2020	Oral temperature (°C)	35.9	38.2	36.6	36.7		36.6	36.4	04JUN2020	1
						Fatigue	N	Mod	N	N		N	N	04JUN2020	1
						Headache	N	Mod	N	N		N	N	04JUN2020	1
						Chills	N	Mild	N	N		N	N	04JUN2020	1
						Vomiting	N	N	N	N		N	N		
						Diarrhea	N	N	N	N		N	N		
						New or worsened muscle pain	N	Mod	N	N		N	N	04JUN2020	1
						New or worsened joint pain	N	Mild	N	N		N	N	04JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No		No	No		
			C4591001 1002 10021006	1	11MAY2020	Oral temperature (°C)	36.7	37	36.7	36.2	36.6	36.6	36.3		
						Fatigue	N	Mod	Mild	N	N	N	Mild	18MAY2020	7
						Headache	N	Mod	Mild	N	N	N	N	13MAY2020	2
						Chills	N	Mod	N	N	N	N	N	12MAY2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	12MAY2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	12MAY2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	02JUN2020	Oral temperature (°C)	38.6	38.6	37	37.1	36.2	36.7	36.7	03JUN2020	2
						Fatigue	N	Mod	Mild	Mild	N	N	N	05JUN2020	3
						Headache	Mild	Mild	Mild	N	N	N	N	04JUN2020	3
						Chills	Mod	Mod	N	N	N	N	N	03JUN2020	2
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	03JUN2020	1
			C4591001 1002 10021014	1	13MAY2020	Oral temperature (°C)	36.6	36.2	36.1	36.2	36.1	36.1			
						Fatigue	Mild	Mild	N	N	N	N		14MAY2020	2

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	14MAY2020	1	
				2	02JUN2020	Oral temperature (°C)	38.4	37.9	36.2	36.8	36.3	36.2	36.3	02JUN2020	1
						Fatigue	Mild	Mod	Mild	N	N	N	N	04JUN2020	3
						Headache	N	Mild	Mild	N	N	N	N	04JUN2020	2
						Chills	Mild	Mild	N	N	N	N	N	03JUN2020	2
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	Yes	Yes	Yes	No	No	No	No	04JUN2020	3
			C4591001 1002 10021015	1	11MAY2020	Oral temperature (°C)	35.7	37.1	35.8	36.2	36.5	36.3	36.2		
						Fatigue	N	Mod	N	N	N	N	N	12MAY2020	1
						Headache	N	Mod	N	N	N	N	N	12MAY2020	1
						Chills	N	Mod	N	N	N	N	N	12MAY2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	Mod	N	N	N	N	N	12MAY2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	12MAY2020	1
				2	02JUN2020	Oral temperature (°C)	38.9	38	37.2	36.2	36.7	36.3	36.3	03JUN2020	2
						Fatigue	Mod	Mod	N	N	N	N	N	03JUN2020	2
						Headache	Mod	Mod	N	N	N	N	N	03JUN2020	2
						Chills	Sev	Mod	N	N	N	N	N	03JUN2020	2
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mod	N	N	N	N	N	03JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	Mod	N	N	N	N	N	03JUN2020	1
						Use of antipyretic or pain medication	Yes	Yes	No	No	No	No	No	03JUN2020	2
			C4591001 1002 10021017	1	13MAY2020	Oral temperature (°C)	36.6	36.1	36.2	36.5	36.8	36.6	36.1		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	Mild	N	N	N	N	N	14MAY2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	14MAY2020	1
				2	02JUN2020	Oral temperature (°C)	37.6	37.3	36.6	36.7	37.1	36.5	36.2		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	Mild	Mild	N	N	N	N	04JUN2020	2
						Chills	Mild	N	N	N	N	N	N	02JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	03JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	Yes	Yes	Yes	No	No	No	No	04JUN2020	3

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1002 10021020	1	13MAY2020	Oral temperature (°C)	36.4	37.4	36.6		36.1	36.6	36.2		
						Fatigue	N	Mod	N		N	N	N	14MAY2020	1
						Headache	N	N	N		N	N	N		
						Chills	N	N	N		N	N	N		
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	Mild	N		N	N	N	14MAY2020	1
						New or worsened joint pain	N	N	N		N	N	N		
						Use of antipyretic or pain medication	No	No	No		No	No	No		
				2	02JUN2020	Oral temperature (°C)	36.6	37.2	36.7	36.7	36.8	36.5	36.1		
						Fatigue	N	Mild	N	N	N	N	N	03JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	Mild	Mod	N	N	N	N	N	03JUN2020	2
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mod	N	N	N	N	N	03JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	Yes	No	No	No	No	No	No	02JUN2020	1
Placebo	18-55	Placebo	C4591001 1001 10011005	1	06MAY2020	Oral temperature (°C)	36.8	36.3	36.8	36.6	37	37	37		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	26MAY2020	Oral temperature (°C)	36.9	37.1	36.8	37	36.8	36.9	37		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1001 10011066	1	29JUN2020	Oral temperature (°C)	36.1	36.1	36.1	36	36.5	37	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	20JUL2020	Oral temperature (°C)	36.7	36.1	36.8	36.8	36.5	36.1			
						Fatigue	N	N	N	N	N	N			
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			
						New or worsened joint pain	N	N	N	N	N	N			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No			
			C4591001 1001 10011069	1	01JUL2020	Oral temperature (°C)	35.6	36.5		36.4		36.4	36.5		
						Fatigue	N	N		N		N	N		
						Headache	N	N		N		N	N		
						Chills	N	N		N		N	N		
						Vomiting	N	N		N		N	N		
						Diarrhea	N	N		N		N	N		
						New or worsened muscle pain	N	N		N		N	N		
						New or worsened joint pain	Mild	N		N		N	N	01JUL2020	1
						Use of antipyretic or pain medication	No	No		No		No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	22JUL2020	Oral temperature (°C)	35.9	35.8		36.4	36.5	36.4	35.9		
						Fatigue	N	N		N	N	N	N		
						Headache	N	N		N	N	N	N		
						Chills	N	N		N	N	N	N		
						Vomiting	N	N		N	N	N	N		
						Diarrhea	N	N		N	N	N	N		
						New or worsened muscle pain	N	N		N	N	N	N		
						New or worsened joint pain	N	N		N	N	N	N		
						Use of antipyretic or pain medication	No	No		No	No	No	No		
			C4591001 1002 10021005	1	04MAY2020	Oral temperature (°C)	36.8	36		36.2	36.2	36.3	36		
						Fatigue	N	N		Mild	N	N	N	07MAY2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N		N	N	N	N		
						Chills	N	N		N	N	N	N		
						Vomiting	N	N		N	N	N	N		
						Diarrhea	N	N		N	N	N	N		
						New or worsened muscle pain	N	N		N	N	N	N		
						New or worsened joint pain	N	N		N	N	N	N		
						Use of antipyretic or pain medication	No	No		No	No	No	No		
				2	26MAY2020	Oral temperature (°C)	36.2	36.3	36.5	36.5	36.5			36.1	
						Fatigue	N	N	N	N	N			N	
						Headache	N	N	N	N	N			N	
						Chills	N	N	N	N	N			N	
						Vomiting	N	N	N	N	N			N	

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N	N		N		
						New or worsened muscle pain	N	N	N	N	N		N		
						New or worsened joint pain	N	N	N	N	N		N		
						Use of antipyretic or pain medication	No	No	No	No	No		No		
			C4591001 1002 10021008	1	06MAY2020	Oral temperature (°C)	36.5	36.2	36	36.2	36.5	36.3	36.4		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	26MAY2020	Oral temperature (°C)	37.1	37.1	36.2	36.8	36.6	36.4	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1002 10021018	1	11MAY2020	Oral temperature (°C)	36.6	36.4	37	36.3	36.4	36.5	36.4		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	Yes	No	No	No	No	No	No	11MAY2020	1
				2	02JUN2020	Oral temperature (°C)	36.4	36.1	36.2	36.3	36.3	35.7			
						Fatigue	N	N	N	N	N	N			
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	No	No	No	No	No			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1002 10021021	1	13MAY2020	Oral temperature (°C)	36.9	36.8	37	37.1	36.9	36.9	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	02JUN2020	Oral temperature (°C)	36	37	37.2	37.1	37	37.1	36.4		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1002 10021022	1	13MAY2020	Oral temperature (°C)	36.3	36.5	36.4	36.7	36.7	36.5	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	Mild	N	N	N	N	N	14MAY2020	1
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	02JUN2020	Oral temperature (°C)		36.5	36.6	36.5	36.3	36.4	36.5		
						Fatigue		Mild	Mild	Mild	Mild	Mild	N	07JUN2020	5
						Headache		N	N	N	N	N	N		
						Chills		N	N	N	N	N	N		
						Vomiting		N	N	N	N	N	N		
						Diarrhea		N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N			
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	No	No	No	No	No			
			C4591001 1002 10021083	1	01JUL2020	Oral temperature (°C)	36.7	37.2	37.1	37.2	36.4	36.7	37.1		
						Fatigue	Mild	Mild	Mod	N	N	N	Mild	10JUL2020	10
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	21JUL2020	Oral temperature (°C)	37.2	37.2	37.2	36.9	37.1	37	36.6		
						Fatigue	Mild	Mild	Mod	N	N	N	N	23JUL2020	3
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
BNT162b1	65-85	10 µg	C4591001 1001 10011037	1	11JUN2020	Use of antipyretic or pain medication	No	No	No	No	No	No	No		
						Oral temperature (°C)	36.7	36.9		36.7	36.6	36.3	36.5		
						Fatigue	N	N		N	N	N	N		
						Headache	N	N		N	Mild	N	N	15JUN2020	1
						Chills	N	N		N	N	N	N		
						Vomiting	N	N		N	N	N	N		
						Diarrhea	N	N		N	N	N	N		
						New or worsened muscle pain	N	N		N	N	N	N		
						New or worsened joint pain	N	N		N	N	N	Mild	18JUN2020	2
						Use of antipyretic or pain medication	No	No		No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	30JUN2020	Oral temperature (°C)	36.4	36.9	36.2	36.7	36.6	36.4	36.4		
						Fatigue	N	Mild	N	N	N	Mild	N	05JUL2020	5
						Headache	N	Mild	N	N	N	Mild	N	05JUL2020	5
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	Mod	N	N	N	N	N	01JUL2020	1
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	01JUL2020	1
			C4591001 1001 10011039	1	09JUN2020	Oral temperature (°C)	36.2	36.1	36.1	35.7	35.7	35.7			
						Fatigue	N	N	N	Mild	N	N		12JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	No	No	No	No	No			
				2	29JUN2020	Oral temperature (°C)	35.7	36.4	36.1	36.1	36.1	36.1	35.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	N	N	N	N	N	N		
					New or worsened joint pain	N	N	N	N	N	N	N		
					Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1001 10011040	1 11JUN2020	Oral temperature (°C)	36.8	36.8	36.4	36.5	36.3	36.1	36.1		
					Fatigue	N	N	N	N	N	N	N		
					Headache	N	N	N	N	N	N	N		
					Chills	N	N	N	N	N	N	N		
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	Mild	N	N	N	N	13JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	02JUL2020	Oral temperature (°C)	35.7	37.3	36.5	36.2	36.5	36.3			
						Fatigue	N	Mod	N	N	N	N		03JUL2020	1
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	Mod	N	N	N	N		03JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	03JUL2020	1	
			C4591001 1001 10011041	1	11JUN2020	Oral temperature (°C)	36.8	36	35.7		35.9	36.4	35.7		
						Fatigue	N	N	N		N	N	N		
						Headache	N	N	N		N	N	N		
						Chills	N	N	N		N	N	N		
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	N	N		N	N	N		
						New or worsened joint pain	N	N	N		N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	Yes	No		No	No	No	12JUN2020	1
				2	02JUL2020	Oral temperature (°C)	36.5		36.2	35.6	36.6	35.7	36.1		
						Fatigue	N		N	N	N	N	N		
						Headache	N		N	N	N	N	N		
						Chills	N		N	N	N	N	N		
						Vomiting	N		N	N	N	N	N		
						Diarrhea	N		N	N	N	N	N		
						New or worsened muscle pain	N		N	N	N	N	N		
						New or worsened joint pain	N		N	N	N	N	N		
						Use of antipyretic or pain medication	No		No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1001 10011044	1	09JUN2020	Oral temperature (°C)	36.4	36.6	36.4	36.4	36.4	35.3	35.8		
						Fatigue	N	N	Mild	N	N	N	N	11JUN2020	1
						Headache	N	N	Mild	N	N	N	N	11JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	10JUN2020	1
						New or worsened joint pain	N	N	Mild	N	N	N	N	11JUN2020	1
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	29JUN2020	Oral temperature (°C)	36.2	37.4	36.2	36.3	36.2	36	36.3		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	Mild	Mod	Mild	N	N	N	N	01JUL2020	3
						Chills	N	Mild	N	N	N	N	N	30JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	Mild	Mod	N	N	N	N	N	30JUN2020	2
						New or worsened joint pain	N	Mild	N	N	N	N	N	30JUN2020	1
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1001 10011045	1	11JUN2020	Oral temperature (°C)	36.2	36.7	36.2	36	36.3	36.2	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	02JUL2020	Oral temperature (°C)	36.3	37.1	36.5	36.5	36.6	36.7	36.4		
						Fatigue	N	Mild	N	N	N	N	N	03JUL2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1002 10021043	1	09JUN2020	Oral temperature (°C)	36.2	36.7	36.3	36.6	36.3	36.4	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	Yes	No	No	No	No	11JUN2020	1
				2	30JUN2020	Oral temperature (°C)	36.4	36.3	36.7	36.4	36.8	36.2	36.2		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	Mild	N	Mild	N	05JUL2020	3
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	Yes	Yes	No	Yes	No	05JUL2020	4
			C4591001 1002 10021044	1	09JUN2020	Oral temperature (°C)	36.6	36.4	36.3	36.2	36.5	36.3	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	30JUN2020	Oral temperature (°C)	37.2	36.5	36.3	36.5	36.2	36.5	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	01JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1002 10021045	1	11JUN2020	Oral temperature (°C)	36.9	36.3	36.4	36.8	36.7	36.1	36.2		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	Mod	N	N	N	N	13JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	Mod	Mild	N	N	15JUN2020	2
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	Yes	No	No	No	No	13JUN2020	1
				2	30JUN2020	Oral temperature (°C)	36.6	36.8	36.4	36.5	36.4	36.3	36.4		
						Fatigue	N	N	N	N	N	N	N		
						Headache	Mild	Mild	Mild	N	Mild	N	N	04JUL2020	5
						Chills	N	Mild	N	N	N	N	N	01JUL2020	1
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	01JUL2020	1
						New or worsened joint pain	N	Mild	N	N	N	N	N	01JUL2020	1
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	01JUL2020	1
			C4591001 1002 10021049	1	11JUN2020	Oral temperature (°C)	36.3	36.1	36.4	36.2	36.4	36.1	36.1		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	30JUN2020	Oral temperature (°C)	36.1	36.7	36.2	36.1	35.7	36.6	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1002 10021052	1	11JUN2020	Oral temperature (°C)	36.7	37.3	37	36.8	37.1	36.2	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	Mild	N	N	N	N	N	12JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	30JUN2020	Oral temperature (°C)	36	36.3	36.6	35.8	36.1	36.7	36.2		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1002 10021053	1	11JUN2020	Oral temperature (°C)	36.6	36.5	36.5	36.5	36.5	36	36.1		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	30JUN2020	Oral temperature (°C)	36.3	36.1	36.2	36.3	36.6	36.8	36.3		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	Mild	N	N	N	N	N	01JUL2020	1
						Chills	N	Mod	N	N	N	N	N	01JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	01JUL2020	1
		20 µg	C4591001 1001 10011043	1	15JUN2020	Oral temperature (°C)	36.4	36.6	36.4	36.7	36.6	36.4	36.4		
						Fatigue	N	Mod	N	N	N	N	N	16JUN2020	1
						Headache	N	Mod	N	N	N	N	N	16JUN2020	1
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36	38.7	37		36.5	36.7		09JUL2020	1
						Fatigue	N	Sev	N		N	N		09JUL2020	1
						Headache	N	Sev	N		N	N		09JUL2020	1
						Chills	N	Mod	N		N	N		09JUL2020	1
						Vomiting	N	N	N		N	N			
						Diarrhea	N	N	N		N	N			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	Mod	N		N	N		09JUL2020	1
						New or worsened joint pain	N	N	N		N	N			
						Use of antipyretic or pain medication	No	Yes	No		No	No		09JUL2020	1
			C4591001 1001 10011049	1	15JUN2020	Oral temperature (°C)	36.5	36.7	36.1	35.9	36.8	36.7	36.7		
						Fatigue	N	N	N	Mod	Mod	Mod	N	20JUN2020	3
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	06JUL2020	Oral temperature (°C)	36.6	37	36.7	36.2	36.3	36.1	36.6		
						Fatigue	N	Mod	Mild	Mild	N	Mild	N	11JUL2020	5
						Headache	N	Mod	N	N	N	N	N	07JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	07JUL2020	1
			C4591001 1001 10011050	17JUN2020	Oral temperature (°C)	37.1	37.4	37.1	37.1	36.7	37	37.1		
					Fatigue	N	N	N	N	N	N	N		
					Headache	N	Mild	N	N	N	N	N	18JUN2020	1
					Chills	N	N	N	N	N	N	N		
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	N	N	N	N	N	N		
					New or worsened joint pain	N	N	N	N	N	N	N		
					Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	18JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	07JUL2020	Oral temperature (°C)	36.7	37.8	37.3	37	36.6	36.9	37.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	Mild	13JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	Yes	Yes	No	12JUL2020	5
			C4591001 1001 10011052	1	17JUN2020	Oral temperature (°C)	36.7	37.6	37.2	37.1	37.6	37	37		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	37.3	37.3	36.8	37.1	37.1	37.2	37.1		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	N	N	N	N	N	N		
					New or worsened joint pain	N	N	N	N	N	N	N		
					Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1001 10011055	1 17JUN2020	Oral temperature (°C)	36.4	37	36.8	35.6	36.5	36	36.7		
					Fatigue	N	Mild	N	N	N	N	N	18JUN2020	1
					Headache	N	N	N	N	N	N	N		
					Chills	N	N	N	N	N	N	N		
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	37.2	37.3	37.1	36.9	37	36.2	36.6		
						Fatigue	N	Mod	N	N	N	N	N	09JUL2020	1
						Headache	N	Mild	N	N	N	N	N	09JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1001 10011059	1	17JUN2020	Oral temperature (°C)	36.3	37.6	36.7	36.8	36.8	36.2	36.3		
						Fatigue	N	Mild	N	N	N	N	Mild	23JUN2020	6
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.2	38.6	37.6	36.5	36.2	36.7	36.3	09JUL2020	1
						Fatigue	N	Mod	N	N	N	N	N	09JUL2020	1
						Headache	N	Mild	N	N	N	N	N	09JUL2020	1
						Chills	N	Mod	N	N	N	N	N	09JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	09JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1002 10021054	1	15JUN2020	Oral temperature (°C)	36.4	36.9	36.1	36.5	36.6	36.2	36.2		
						Fatigue	N	Mild	N	N	N	N	N	16JUN2020	1
						Headache	N	Mod	N	N	N	N	N	16JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	Mild	N	N	N	Mild	21JUN2020	6
						New or worsened joint pain	N	N	N	N	N	N	Mild	21JUN2020	1
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	16JUN2020	1
				2	07JUL2020	Oral temperature (°C)	36.3	38.2	36.9	36.4	36.5	36.3	36.6	08JUL2020	1
						Fatigue	Mild	Mild	N	N	N	N	N	08JUL2020	2

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	Mild	Mod	Mild	N	N	N	N	09JUL2020	3
						Chills	N	Mild	N	N	N	N	N	08JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	08JUL2020	1
			C4591001 1002 10021060	1	15JUN2020	Oral temperature (°C)	37.7	37.3		37.1	37.2	37	36.7		
						Fatigue	N	N		N	N	N	N		
						Headache	N	N		N	N	N	N		
						Chills	Mild	Mild		N	N	N	N	17JUN2020	3

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N		N	N	N	N		
						Diarrhea	N	N		N	N	Mild	N	20JUN2020	1
						New or worsened muscle pain	N	Sev		N	N	N	N	17JUN2020	2
						New or worsened joint pain	N	N		N	N	N	N		
						Use of antipyretic or pain medication	No	Yes		No	No	No	No	16JUN2020	1
				2	07JUL2020	Oral temperature (°C)	36.8	37.6	36.6	36.8	36.9	37	37.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	Mild	Mild	N	N	N	N	N	08JUL2020	2
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	08JUL2020	1
			C4591001 1002 10021064	1	17JUN2020	Oral temperature (°C)	36.7	37.6	36.8	36.4	36.8	36.7	37		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.7	38.1	36.9					09JUL2020	1
						Fatigue	N	Mod	N					09JUL2020	1
						Headache	N	Mod	N					09JUL2020	1
						Chills	N	Mild	N					09JUL2020	1
						Vomiting	N	N	N						
						Diarrhea	N	N	N						
						New or worsened muscle pain	N	Mod	N					09JUL2020	1
						New or worsened joint pain	N	Mild	N					09JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	Yes	No					09JUL2020	1
			C4591001 1002 10021067	1	17JUN2020	Oral temperature (°C)	36.6	36.2	36.1	36.2	36	36.1	35.8		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	08JUL2020	Oral temperature (°C)	36.3	37	36.7	36.5	36.8	36.2	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1002 10021068	1	17JUN2020	Oral temperature (°C)	36.4	37	36.6	36.8	36.8	36.9	36.6		
						Fatigue	N	Mild	N	N	N	N	N	18JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.7	38.6	37.2	36.7	36.7	36.6	36.8	09JUL2020	1
						Fatigue	N	Mod	N	N	N	N	N	09JUL2020	1
						Headache	N	Mild	N	N	N	N	N	09JUL2020	1
						Chills	N	Mod	N	N	N	N	N	09JUL2020	1
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	Mild	N	N	N	N	N	09JUL2020	1
					New or worsened joint pain	N	N	Mild	N	N	N	N	10JUL2020	1
					Use of antipyretic or pain medication	Yes	Yes	Yes	No	No	No	No	10JUL2020	3
			C4591001 1002 10021071	1	17JUN2020	Oral temperature (°C)	36.3	36.8	36.4	36.5	36.1	36.2	36.1	
					Fatigue	N	Mild	N	N	N	N	N	18JUN2020	1
					Headache	N	Mild	N	N	N	N	N	18JUN2020	1
					Chills	N	N	N	N	N	N	N		
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	18JUN2020	1
				2	08JUL2020	Oral temperature (°C)	35.9	38.1	36.2	36.5	36.2	36.1	35.9	09JUL2020	1
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	Mod	N	N	N	N	N	09JUL2020	1
						Chills	N	Mild	N	N	N	N	N	09JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	Mild	N	N	N	N	N	09JUL2020	1
						New or worsened muscle pain	N	Mod	N	N	N	N	N	09JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	Mod	N	N	N	N	N	09JUL2020	1
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	09JUL2020	1
		30 µg	C4591001 1001 10011046	1	18JUN2020	Oral temperature (°C)	36.5	37.7	36.6	36.3	36.2	36.7	36.1		
						Fatigue	N	Mod	N	N	N	N	N	19JUN2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	19JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	09JUL2020	Oral temperature (°C)	36.5	38	36.6	36.7		36.8	36.4	10JUL2020	1
						Fatigue	N	Mod	N	N		N	N	10JUL2020	1
						Headache	N	Mild	N	N		N	N	10JUL2020	1
						Chills	N	N	N	N		N	N		
						Vomiting	N	N	N	N		N	N		
						Diarrhea	N	N	N	N		N	N		
						New or worsened muscle pain	N	Mild	N	N		N	N	10JUL2020	1
						New or worsened joint pain	N	Mild	N	N		N	N	10JUL2020	1
						Use of antipyretic or pain medication	No	No	No	No		No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1001 10011048	1	16JUN2020	Oral temperature (°C)	37.6	37.7	37	36.8	36.8	37.1	36.4		
						Fatigue	N	Sev	Mild	N	N	N	N	18JUN2020	2
						Headache	Mod	Mild	N	N	N	N	N	17JUN2020	2
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	Yes	Yes	No	No	No	No	No	17JUN2020	2
				2	08JUL2020	Oral temperature (°C)	37.1	38.9	37.6	36.7	36.7	36.5	36.7	09JUL2020	1
						Fatigue	Mild	Sev	Mild	N	N	Mild	Mild		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	Mod	Mod	N	N	Mild	Mild	N	13JUL2020	6
						Chills	Mild	Mod	N	N	N	N	N	09JUL2020	2
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	Yes	Yes	No	No	Yes	No	No	12JUL2020	5
			C4591001 1001 10011058	1	18JUN2020	Oral temperature (°C)	37.7	37.5	36.4	36.8	36.6	36.6	37.1		
						Fatigue	Mild	Mild	Mild	N	N	N	N	20JUN2020	3
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	09JUL2020	Oral temperature (°C)	36.8	38.4	37.6	36.5	36.1	36.6	36.5	10JUL2020	1
						Fatigue	Mild	Mod	N	N	N	N	N	10JUL2020	2
						Headache	N	Mild	N	N	N	N	N	10JUL2020	1
						Chills	N	Mild	N	N	N	N	N	10JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	Yes	No	No	No	No	11JUL2020	2
			C4591001 1001 10011061	1	18JUN2020	Oral temperature (°C)	36.2	37.1	36.5	36.7	36.5	36.5	36.3		
						Fatigue	N	N	N	N	N	N	Mild	27JUN2020	4
						Headache	N	Mild	N	N	N	N	N	19JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	19JUN2020	1
				2	09JUL2020	Oral temperature (°C)	36.6	37.2	36.9	36.2	36.2	36.2	36.4		
						Fatigue	N	N	N	N	N	N	N		
						Headache	Mild	Mild	N	N	N	N	N	10JUL2020	2
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	10JUL2020	1
			C4591001 1001 10011063	1	18JUN2020	Oral temperature (°C)	37.9	37.3	36.6	36.7	36.6	36.1			
						Fatigue	N	N	N	N	N	N			
						Headache	Mild	Mild	N	N	N	N	20JUN2020	2	
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	Mild	Mild	N	N	N	N	20JUN2020	2	
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	Yes	Yes	No	No	No	No	20JUN2020	2	

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	07JUL2020	Oral temperature (°C)	37.4	37.9	35.5	36.5	36.7	36.6	35.1		
						Fatigue	N	Mod	N	N	N	N	N	08JUL2020	1
						Headache	N	Mod	N	N	N	N	N	08JUL2020	1
						Chills	Mod	Mild	N	N	N	N	N	08JUL2020	2
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	08JUL2020	1
			C4591001 1002 10021059	1	15JUN2020	Oral temperature (°C)	36.7	36.8	36.8	36.7	37	36.5	36.6		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	07JUL2020	Oral temperature (°C)	37.2	36.8	37.1	36.3	36.2		36.4		
						Fatigue	N	N	N	N	N		N		
						Headache	N	N	N	N	N		N		
						Chills	N	N	N	N	N		N		
						Vomiting	N	N	N	N	N		N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N	N		N		
						New or worsened muscle pain	N	N	N	N	N		N		
						New or worsened joint pain	N	N	N	N	N		N		
						Use of antipyretic or pain medication	No	No	No	No	No		No		
			C4591001 1002 10021062	1	15JUN2020	Oral temperature (°C)	37.1	38.2	37.3	37.1	36.8	36.7	37	16JUN2020	1
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	Mild	N	N	N	N	N	16JUN2020	1
						Chills	N	Mild	N	Mild	N	N	N	18JUN2020	3
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	16JUN2020	1
				2	07JUL2020	Oral temperature (°C)	36.6	38.3	37.8	37.4	36.7	36.3	37	08JUL2020	1
						Fatigue	N	Mod	N	Mod	Mild	Mild	N	12JUL2020	5
						Headache	N	Mod	N	N	N	N	N	08JUL2020	1
						Chills	N	Mod	N	N	N	N	N	08JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	Mild	N	N	11JUL2020	1
						New or worsened muscle pain	N	Mod	N	N	N	N	N	08JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	Mod	N	N	N	N	N	08JUL2020	1
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	08JUL2020	1
			C4591001 1002 10021063	1	15JUN2020	Oral temperature (°C)	36.6	36.9	36.4	36.8	36.6	36.5	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	Mild	N	Mod	Mod	Mod	Mild	N	20JUN2020	6

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	Yes	No	20JUN2020	1
				2	07JUL2020	Oral temperature (°C)	36.6	36.6	36.6	36.6	36.3	36.3	37		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1002 10021069	1	18JUN2020	Oral temperature (°C)	35.9	36.3	36.1	36.2	36.1	35.9			
						Fatigue	N	N	N	N	N	N			
						Headache	N	Mild	Mild	N	N	N	20JUN2020	2	
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	Mod	Mild	Mild	N	N	21JUN2020	3	
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	19JUN2020	1	
				2	08JUL2020	Oral temperature (°C)	35.7	36.3	35.8	36.3	35.9	35.9	36.2		
						Fatigue	N	Mild	N	N	N	Mild	Mild	15JUL2020	7

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	Mild	N	N	N	N	N	09JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mod	N	N	N	N	N	09JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	09JUL2020	1
			C4591001 1002 10021074	1	18JUN2020	Oral temperature (°C)	37.6	38.6	37	37.3	37.1	36.6	36.9	19JUN2020	1
						Fatigue	N	Mild	Mild	N	Mod	N	N	22JUN2020	4
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	Yes	No	No	No	21JUN2020	1
				2	08JUL2020	Oral temperature (°C)	37.8		37.8	36.9	37.2	36.6	36.8		
						Fatigue	N		N	N	N	N	N		
						Headache	N		N	N	N	N	N		
						Chills	N		N	N	N	N	N		
						Vomiting	N		N	N	N	N	N		
						Diarrhea	N		N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N		N	N	N	N	N		
						New or worsened joint pain	N		N	N	N	N	N		
						Use of antipyretic or pain medication	No		No	No	No	No	No		
			C4591001 1002 10021075	1	18JUN2020	Oral temperature (°C)	36.2	36.5	36.7	36.8	36.6	36.7	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	Mod	N	N	N	N	N	19JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	19JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	19JUN2020	1
				2	08JUL2020	Oral temperature (°C)	37	37.7	36.4	36.5	36.7	36.5	36.6		
						Fatigue	N	Mild	N	N	N	N	N	09JUL2020	1
						Headache	Mild	Mild	N	N	N	N	N	09JUL2020	2
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	09JUL2020	1
			C4591001 1002 10021077	1	18JUN2020	Oral temperature (°C)	35.8	38.3	36.4	35.9	36.8	35.8	36.2	19JUN2020	1
						Fatigue	N	Mod	N	N	N	N	N	19JUN2020	1
						Headache	N	Mild	N	N	N	N	N	19JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	19JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	19JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	08JUL2020	Oral temperature (°C)	35.7	36.8	37.8	36.9	36.2	36.7	36.3		
						Fatigue	N	Mild	Mild	N	N	N	N	10JUL2020	2
						Headache	N	Mild	Mild	N	N	N	N	10JUL2020	2
						Chills	N	N	N	N	N	N	N		
						Vomiting	Mild	N	N	N	N	N	N	08JUL2020	1
						Diarrhea	Mild	N	N	N	N	N	N	08JUL2020	1
						New or worsened muscle pain	Mild	N	N	N	N	N	N	08JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	Yes	No	No	No	No	10JUL2020	2
Placebo	65-85	Placebo	C4591001 1001 10011042	1	11JUN2020	Oral temperature (°C)	36.6	36.7	37	36.2	36.6	36.8	36.3		
						Fatigue	N	Mild	Mod	N	N	N	N	13JUN2020	2

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	Mild	N	N	N	N	13JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	Mild	N	N	N	N	13JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	30JUN2020	Oral temperature (°C)	36.7	36.5	36.8	36.9	36.6	36.6	36.8		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	N	N	N	N	N	N		
					New or worsened joint pain	N	N	N	N	N	N	N		
					Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1001 10011053	1 16JUN2020	Oral temperature (°C)	35.7	35.6	36.3	35.8	36.2	36.1	36.3		
					Fatigue	N	Mild	N	N	N	N	N	17JUN2020	1
					Headache	N	N	N	N	N	N	N		
					Chills	N	N	N	N	N	N	N		
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	09JUL2020	Oral temperature (°C)	35.8	36.2	35.6	36	35.8	36.1	35.9		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1001 10011057	1	17JUN2020	Oral temperature (°C)	36.6	36.8	36.8	36.6	36.6	36.4	36.5		
						Fatigue	Mild	Mild	N	N	N	N	N	18JUN2020	2
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.6	36.7	36.7	36.5	36.9	36.5	36.5		
						Fatigue	Mild	N	N	N	N	N	N	08JUL2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1001 10011064	1	18JUN2020	Oral temperature (°C)	36.3	36.5	36.3	36.3	36.2	36	35.9		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	07JUL2020	Oral temperature (°C)	36.2	36.1	36.8	35.6	36.1	36.6			
						Fatigue	N	N	N	N	N	N			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	No	No	No	No	No			
			C4591001 1002 10021042	1	09JUN2020	Oral temperature (°C)	37.1	36.3	36.3	36.1	36.2	36.6	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	30JUN2020	Oral temperature (°C)	36.6	36.4	36.6		36.1	37	36.5		
						Fatigue	N	N	N		N	N	N		
						Headache	N	N	N		N	N	N		
						Chills	N	N	N		N	N	N		
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N		N	N	N		
						New or worsened joint pain	N	N	N		N	N	N		
						Use of antipyretic or pain medication	No	No	No		No	No	No		
			C4591001 1002 10021047	1	11JUN2020	Oral temperature (°C)	36.3	35.6	36.2	36	36.3	36.3	36.8		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	30JUN2020	Oral temperature (°C)	36.7	36.7	36.8	36.3	36.3	36.2	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1002 10021050	1	15JUN2020	Oral temperature (°C)	36.2	36.6	36.7	36.8	36.8	36.9	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	07JUL2020	Oral temperature (°C)	36.5	37	36.8	37.4	36.5	37.1	36.7		
						Fatigue	N	N	N	N	Mod	N	N	11JUL2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1002 10021072	1	18JUN2020	Oral temperature (°C)	37	36.9	36.2	36.9		36.9	36.6		
						Fatigue	N	N	N	N		N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N		N	N		
						Chills	N	N	N	N		N	N		
						Vomiting	N	N	N	N		N	N		
						Diarrhea	N	N	N	N		N	N		
						New or worsened muscle pain	N	N	N	N		N	N		
						New or worsened joint pain	N	N	N	N		N	N		
						Use of antipyretic or pain medication	No	No	No	No		No	No		
				2	08JUL2020	Oral temperature (°C)	36.3	36.7	36.2	36.8	36.2	36.3	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	Mild	N	N	N	11JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	Yes	No	No	No	11JUL2020	1
			C4591001 1002 10021073	1	17JUN2020	Oral temperature (°C)	36.4	36.8	36.9	36.5	36.6	37.1	36.9		
						Fatigue	N	Mild	N	N	N	N	N	18JUN2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	Mild	N	N	N	N	N	18JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.9	36.4	36.6	36.4	37.2	36.7			
						Fatigue	N	N	N	N	N	N			
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
BNT162b2	18-55	10 µg	C4591001 1003 10031018	1	09JUN2020	New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	No	No	No	No	No			
						Oral temperature (°C)	37.1	37.1	36.8	36.8	36.8	36.5	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	Mild	16JUN2020	2
						New or worsened joint pain	N	N	N	N	N	N	Mild	16JUN2020	2

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	30JUN2020	Oral temperature (°C)	36.7	37.7	37.1	36.6	37.2	36.7	37		
						Fatigue	Mild	Mild	Mild	Mild	N	N	N	03JUL2020	4
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	Mild	N	N	N	N	N	N	30JUN2020	1
						New or worsened joint pain	N	Mild	N	N	N	N	N	01JUL2020	1
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1003 10031019	1	11JUN2020	Oral temperature (°C)	36.3	36.2	35.7	37	36.3	36	36		
						Fatigue	N	N	N	Mild	N	N	N	14JUN2020	1
						Headache	N	N	Mild	N	N	N	N	13JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	02JUL2020	Oral temperature (°C)	36.3	36.3	36	36.1	36	36.2	37		
						Fatigue	N	Mild	N	N	N	N	N	03JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c	
							1	2	3	4	5	6	7			
						Headache	N	Mild	N	N	N	N	N	N	03JUL2020	1
						Chills	N	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No	No		
			C4591001 1003 10031020	1	11JUN2020	Oral temperature (°C)	36.6	36.6	36.3		36.3	36.4	36.5			
						Fatigue	N	N	N		N	N	N			
						Headache	N	N	N		N	N	N			
						Chills	N	N	N		N	N	N			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	N	N		N	N	N		
						New or worsened joint pain	N	N	N		N	N	N		
						Use of antipyretic or pain medication	No	No	No		Yes	Yes	No	16JUN2020	2
				2	02JUL2020	Oral temperature (°C)	36.8	36.6	36.3		36.3	36.3	36.5		
						Fatigue	N	N	N		N	N	N		
						Headache	N	N	N		N	N	N		
						Chills	N	N	N		N	N	N		
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N		N	N	N		
						New or worsened joint pain	N	N	N		N	N	N		
						Use of antipyretic or pain medication	No	No	No		No	No	No		
			C4591001 1003 10031021	1	09JUN2020	Oral temperature (°C)	36.7	36.1	36.5	36.1	36.2	36.7	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	30JUN2020	Oral temperature (°C)	36.1	37.8	36.7	36.5	36.5	36.2	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	Mod	N	N	N	N	N	01JUL2020	1
						Chills	N	Mod	N	N	N	N	N	01JUL2020	1
						Vomiting	N	Mild	N	N	N	N	N	01JUL2020	1
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	01JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	01JUL2020	1
			C4591001 1003 10031022	1	11JUN2020	Oral temperature (°C)	36.4	36.1		35.6	36	35.9	35.9		
						Fatigue	N	N		Mild	N	N	N	14JUN2020	1
						Headache	N	N		Mild	N	N	N	14JUN2020	1
						Chills	N	N		N	N	N	N		
						Vomiting	N	N		N	N	N	N		
						Diarrhea	N	N		N	N	N	N		
						New or worsened muscle pain	N	N		N	N	N	N		
						New or worsened joint pain	N	N		N	N	N	N		
						Use of antipyretic or pain medication	No	No		Yes	No	No	No	14JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	02JUL2020	Oral temperature (°C)	36.3	37	36.4	36.4	36.2	36.7	36.2		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031024	1	11JUN2020	Oral temperature (°C)	36.1	35.9	35.8	36.1	35.8	36.7	36.2		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	02JUL2020	Oral temperature (°C)	36.7	36.2	36.6	36.6	36.3		36.3		
						Fatigue	N	N	N	N	N		N		
						Headache	N	N	N	N	N		N		
						Chills	N	N	N	N	N		N		
						Vomiting	N	N	N	N	N		N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N	N	N	N			N	
					New or worsened muscle pain	N	N	N	N	N			N	
					New or worsened joint pain	N	N	N	N	N			N	
					Use of antipyretic or pain medication	No	No	No	No	No			No	
			C4591001 1007 10071014	1 11JUN2020	Oral temperature (°C)	37.2	37	36.8	36.4	36.7	36.5	36.3		
					Fatigue	N	N	N	N	N	N	N	N	
					Headache	N	N	N	N	N	N	N	N	
					Chills	N	N	N	N	N	N	N	N	
					Vomiting	N	N	N	N	N	N	N	N	
					Diarrhea	N	N	N	N	N	N	N	N	

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	Mild	N	N	N	N	13JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	01JUL2020	Oral temperature (°C)	37.3	36.7	36.6	36.8	36.6	36.6	36.4		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071015	1	08JUN2020	Oral temperature (°C)	36.5	36.9	36.9	36.6	36.2	35.8	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	29JUN2020	Oral temperature (°C)	36.9	35.6	36.7	35.7	36.6	36.3			
						Fatigue	N	N	N	N	N	N			
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	No	No	No	No	No			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1007 10071016	1	10JUN2020	Oral temperature (°C)	37.1	36.7	37.1	37.1	36.2	36.7	37		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	Mild	N	N	N	13JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	Mild	17JUN2020	2
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	01JUL2020	Oral temperature (°C)	37	36.8	36.5	36.2	35.7	36.4	36.1		
						Fatigue	Mild	N	N	N	Mild	N	Mild	08JUL2020	8

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071019	1	08JUN2020	Oral temperature (°C)	37.1	36.4	36.2	35.8	36.3	36.3	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	29JUN2020	Oral temperature (°C)	36.3	36.8	36.5	36.2	36.6	36.6	36.8		
						Fatigue	N	N	N	N	N	Mod	N	04JUL2020	1
						Headache	N	N	N	Mild	Mod	Mod	Mod	09JUL2020	8
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071021	1	10JUN2020	Oral temperature (°C)	36.5	36.8	36.2	37.1	36.6	36.8	36.8		
						Fatigue	Mild	N	N	N	N	N	N	10JUN2020	1
						Headache	Mild	N	N	N	N	N	N	10JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	01JUL2020	Oral temperature (°C)	37	37.2	37.1	37.1			37.1		
						Fatigue	N	N	N	N			N		
						Headache	N	N	N	N			N		
						Chills	N	N	N	N			N		
						Vomiting	N	N	N	N			N		
						Diarrhea	N	N	N	N			N		
						New or worsened muscle pain	N	N	N	N			N		
						New or worsened joint pain	N	N	N	N			N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No		No			
			C4591001 1007 10071022	1	10JUN2020	Oral temperature (°C)	37	37.1	36.2	36.8		36.9	36.9		
						Fatigue	N	N	N	N		N	N		
						Headache	N	N	N	N		N	N		
						Chills	N	N	N	N		N	N		
						Vomiting	N	N	N	N		N	N		
						Diarrhea	N	N	N	N		N	N		
						New or worsened muscle pain	N	N	N	N		N	N		
						New or worsened joint pain	N	N	N	N		N	N		
						Use of antipyretic or pain medication	No	No	No	No		No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	01JUL2020	Oral temperature (°C)	37.1	37.3	37.3	37.2	37.3	37.3	37.4		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
		20 µg	C4591001 1003 10031026	1	17JUN2020	Oral temperature (°C)	35.9	35.9	36.9		36.5	35.7	36		
						Fatigue	N	N	N		N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N		N	N	N		
						Chills	N	N	N		N	N	N		
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	N	N		N	N	N		
						New or worsened joint pain	N	N	N		N	N	N		
						Use of antipyretic or pain medication	No	No	No		No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.7	36.5		35.8	35.8	35.6	36.1		
						Fatigue	N	N		N	N	N	N		
						Headache	N	N		N	N	N	N		
						Chills	N	N		N	N	N	N		
						Vomiting	N	N		N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N		N	N	N	N		
					New or worsened muscle pain	N	N		N	N	N	N		
					New or worsened joint pain	N	N		N	N	N	N		
					Use of antipyretic or pain medication	No	No		No	No	No	No		
			C4591001 1003 10031027	1 15JUN2020	Oral temperature (°C)	37	36.7	37.1	36.6	36.6	37.1	36.9		
					Fatigue	N	N	N	N	N	N	N		
					Headache	N	N	N	N	N	N	N		
					Chills	N	N	N	N	N	N	N		
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	06JUL2020	Oral temperature (°C)	36.7	36.2	36.8	36.6		36.9	36.6		
						Fatigue	N	N	N	N		N	N		
						Headache	N	N	N	N		N	N		
						Chills	N	N	N	N		N	N		
						Vomiting	N	N	N	N		N	N		
						Diarrhea	N	N	N	N		N	N		
						New or worsened muscle pain	N	N	N	N		N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N		N	N		
						Use of antipyretic or pain medication	No	No	No	No		No	No		
			C4591001 1003 10031028	1	15JUN2020	Oral temperature (°C)	36.1	36.4	36.3	36.6	36.1	36.3	36.2		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	Mod	N	20JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	Yes	No	20JUN2020	1
				2	06JUL2020	Oral temperature (°C)	36.2	37.9	36.4	36.4	36.5	36.3	36.2		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	Mild	N	N	N	N	N	N	06JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	07JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1003 10031030	1	17JUN2020	Oral temperature (°C)	36.7	36.7	36.8	36.2	36.6	36.5	36.4		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.2	36.2	36.3	36.3	37	36.3	36.4		
						Fatigue	Mild	N	Mild	N	N	N	N	10JUL2020	3

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031032	1	17JUN2020	Oral temperature (°C)	36.4	36.5	36.7	36.6	36.5	36.7	36.7		
						Fatigue	Mild	Mild	Mild	N	N	N	N	19JUN2020	3
						Headache	N	Mild	N	N	N	N	N	18JUN2020	1
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	18JUN2020	1
				2	08JUL2020	Oral temperature (°C)	36.6	37.6	36.4	36.5	36.5	36.6	36.5		
						Fatigue	Mod	Mod	N	N	N	N	N	09JUL2020	2
						Headache	N	Mild	N	N	N	N	N	09JUL2020	1
						Chills	N	Mild	N	N	N	N	N	09JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	Mod	N	N	N	N	N	09JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031038	1	17JUN2020	Oral temperature (°C)	36.6	36.3	36.7	36.3	36.6	36.2	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.6	37.6	36.6	36.5	36.7	36.6	36.6		
						Fatigue	N	Mild	N	N	N	N	N	09JUL2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	Mod	N	N	N	N	N	09JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mod	N	N	N	N	N	09JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071017	1	15JUN2020	Oral temperature (°C)	35.9	35.8	35.9		36.2	36.5	36.4		
						Fatigue	N	N	N		N	N	N		
						Headache	N	N	N		N	N	N		
						Chills	N	N	N		N	N	N		
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	Mild	N		N	N	N	16JUN2020	1
						New or worsened joint pain	N	N	N		N	N	N		
						Use of antipyretic or pain medication	Yes	No	No		No	No	No	15JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	06JUL2020	Oral temperature (°C)	36.4	35.2	36.3	36.5	36.6	35.8	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mod	N	N	N	N	N	07JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	Yes	Yes	No	No	No	No	No	07JUL2020	2
			C4591001 1007 10071023	1	17JUN2020	Oral temperature (°C)	36.4	36.4	36.3	36.2	36.4		36.6		
						Fatigue	Mild	Mild	N	N	N		N	18JUN2020	2

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N		N		
						Chills	N	N	N	N	N		N		
						Vomiting	N	N	N	N	N		N		
						Diarrhea	N	N	N	N	N		N		
						New or worsened muscle pain	N	N	N	N	N		N		
						New or worsened joint pain	N	N	N	N	N		N		
						Use of antipyretic or pain medication	No	No	No	No	No		No		
				2	08JUL2020	Oral temperature (°C)	37.3	37.2	36.6	37.1	36.6	36.6	36.6		
						Fatigue	Mod	Mild	N	N	N	N	N	09JUL2020	2
						Headache	Mild	Mild	N	N	N	N	N	09JUL2020	2
						Chills	Mild	N	N	N	N	N	N	08JUL2020	1
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071026	1	15JUN2020	Oral temperature (°C)	37.1	37.1	37.1	37.1	36.8		36.6		
						Fatigue	N	Mild	N	N	N		N	16JUN2020	1
						Headache	N	N	N	N	N		N		
						Chills	N	N	N	N	N		N		
						Vomiting	N	N	N	N	N		N		
						Diarrhea	N	N	N	N	N		N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N		N		
						New or worsened joint pain	N	N	N	N	N		N		
						Use of antipyretic or pain medication	No	No	No	No	No		No		
				2	06JUL2020	Oral temperature (°C)	37.7	36.4	36.4	36.3	36.8	36.4	36.4		
						Fatigue	Mod	Mild	N	N	N	N	N	07JUL2020	2
						Headache	N	N	N	N	N	N	N		
						Chills	Mod	N	N	N	N	N	N	06JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	Yes	Yes	No	No	No	No	No	07JUL2020	2
			C4591001 1007 10071027	1	17JUN2020	Oral temperature (°C)	36.4	36.6			36.7		36.3		
						Fatigue	N	Mod			N		N	18JUN2020	1
						Headache	N	N			N		N		
						Chills	N	N			N		N		
						Vomiting	N	N			N		N		
						Diarrhea	N	N			N		N		
						New or worsened muscle pain	N	Mod			N		N	18JUN2020	1
						New or worsened joint pain	N	N			N		N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No		No		No			
				2	08JUL2020	Oral temperature (°C)	36.7	38.3		36.8	36.6	36.3		09JUL2020	1
						Fatigue	Mod	Sev		Mild	N	N		11JUL2020	4
						Headache	N	Mod		N	N	N		09JUL2020	1
						Chills	N	Mod		N	N	N		09JUL2020	1
						Vomiting	N	N		N	N	N			
						Diarrhea	N	N		N	N	N			
						New or worsened muscle pain	Mild	Mod		N	N	N		09JUL2020	2
						New or worsened joint pain	N	N		N	N	N			
						Use of antipyretic or pain medication	No	Yes		No	No	No		09JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1007 10071029	1	17JUN2020	Oral temperature (°C)	36.5	36.8		36.5	36.2	36.6	36.3		
						Fatigue	Mild	N		N	N	N	N	17JUN2020	1
						Headache	N	Mild		N	N	N	N	18JUN2020	1
						Chills	N	N		N	N	N	N		
						Vomiting	N	N		N	N	N	N		
						Diarrhea	Mild	N		N	N	N	N	17JUN2020	1
						New or worsened muscle pain	N	N		N	N	N	N		
						New or worsened joint pain	N	N		N	N	N	N		
						Use of antipyretic or pain medication	No	Yes		No	No	No	No	18JUN2020	1
				2	08JUL2020	Oral temperature (°C)	36.8	37.4	36.9	36.4	36.4	36.7	36.8		
						Fatigue	Mild	N	N	N	N	N	N	08JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c	
							1	2	3	4	5	6	7			
						Headache	N	Mild	N	N	N	N	N	N	09JUL2020	1
						Chills	N	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	No	09JUL2020	1
			C4591001 1007 10071040	1	17JUN2020	Oral temperature (°C)	36.8	36.4	36.3	36.2	36.3	36.6	36.8			
						Fatigue	N	N	N	N	N	N	N	N		
						Headache	N	N	N	Mild	N	N	N	N	20JUN2020	1
						Chills	N	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	Yes	No	No	No	20JUN2020	1
				2	08JUL2020	Oral temperature (°C)	36.5	36.2	36.4	36.2		36.4	36.6		
						Fatigue	N	N	N	N		N	N		
						Headache	N	N	N	N		N	N		
						Chills	N	N	N	N		N	N		
						Vomiting	N	N	N	N		N	N		
						Diarrhea	N	N	N	N		N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N		N	N		
						New or worsened joint pain	N	N	N	N		N	N		
						Use of antipyretic or pain medication	No	No	No	No		No	No		
		30 µg	C4591001 1003 10031057	1	24JUN2020	Oral temperature (°C)	36.8	36.4	36.3	36.8	36.5	36.5	36.1		
						Fatigue	Mod	Mod	N	N	N	N	N	25JUN2020	2
						Headache	Mild	Mod	N	N	N	N	N	25JUN2020	2
						Chills	Mild	N	N	N	N	N	N	24JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	25JUN2020	1
				2	15JUL2020	Oral temperature (°C)	36.8	36.6	36.6	36.4	36.6	36.4	36.6		
						Fatigue	N	Mild	N	N	N	N	N	16JUL2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031059	1	24JUN2020	Oral temperature (°C)	35.7	36.2	36.3	35.6	35.7	35.3	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	15JUL2020	Oral temperature (°C)	35.8	36.3	36.2	35.7	36	36.3	36.3		
						Fatigue	N	Mild	N	N	N	N	N	16JUL2020	1
						Headache	N	Mild	N	N	N	N	N	16JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	16JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	16JUL2020	1
			C4591001 1003 10031061	1	22JUN2020	Oral temperature (°C)	36.4	38	36.2	35.9	36.3	36.3	36.6	23JUN2020	1
						Fatigue	Mod	Sev	N	N	N	N	N	23JUN2020	2

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c	
							1	2	3	4	5	6	7			
						Headache	N	Mod	N	N	N	N	N	N	23JUN2020	1
						Chills	N	Mod	N	N	N	N	N	N	23JUN2020	1
						Vomiting	N	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N	N			
						New or worsened muscle pain	N	Mod	N	N	N	N	N	N	23JUN2020	1
						New or worsened joint pain	N	Mod	N	N	N	N	N	N	23JUN2020	1
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	No	23JUN2020	1
				2	13JUL2020	Oral temperature (°C)	36.9	37.9	36.4	36.3	36.4	36.5				
						Fatigue	N	Mod	N	N	N	N			14JUL2020	1
						Headache	N	Mod	Mild	N	N	N			15JUL2020	2
						Chills	N	Mod	N	N	N	N			14JUL2020	1
						Vomiting	N	N	N	N	N	N				

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N	N	N	N	N			
					New or worsened muscle pain	N	Mod	N	N	N	N	14JUL2020	1	
					New or worsened joint pain	N	Mod	N	N	N	N	14JUL2020	1	
					Use of antipyretic or pain medication	No	Yes	No	No	No	No	14JUL2020	1	
			C4591001 1003 10031065	1 24JUN2020	Oral temperature (°C)	36.7	37.3	36.7	36.6	36.6	36.6	36.6		
					Fatigue	N	N	N	N	N	N	N		
					Headache	N	N	N	N	N	N	N		
					Chills	N	N	N	N	N	N	N		
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	15JUL2020	Oral temperature (°C)	36.6	38.7	37.2	36.3	36.1	36.7	36.7	16JUL2020	1
						Fatigue	N	Sev	Mild	N	N	N	N	17JUL2020	2
						Headache	N	Mod	Mild	Mild	N	Mild	N	20JUL2020	5
						Chills	N	Mild	N	N	N	N	N	16JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031066	1	22JUN2020	Oral temperature (°C)	36.8	37	36.7	36.3	36.5		36.4		
						Fatigue	N	N	N	N	N		N		
						Headache	N	N	N	N	N		N		
						Chills	N	N	N	N	N		N		
						Vomiting	N	N	N	N	N		N		
						Diarrhea	N	N	N	N	N		N		
						New or worsened muscle pain	N	N	N	N	N		N		
						New or worsened joint pain	N	N	N	N	N		N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No		No		
				2	13JUL2020	Oral temperature (°C)	36.6	36.6	37.1	36.6	36.7	36.5	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	Mild	Mild	Mild	N	N	17JUL2020	3
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1003 10031072	1	24JUN2020	Oral temperature (°C)	36.8	37	36.6	36.6	36.6	36.8	36.3		
						Fatigue	N	Mod	N	N	N	N	N	25JUN2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	Mod	N	N	N	N	N	25JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mod	N	N	N	N	N	25JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	Yes	30JUN2020	1
				2	16JUL2020	Oral temperature (°C)	36.5	36.8	36.5	36.6		36.3	36.5		
						Fatigue	N	Mod	N	N		N	N	17JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N		N	N		
						Chills	N	Mod	N	N		N	N	17JUL2020	1
						Vomiting	N	N	N	N		N	N		
						Diarrhea	N	N	N	N		N	N		
						New or worsened muscle pain	N	N	N	N		N	N		
						New or worsened joint pain	N	N	N	N		N	N		
						Use of antipyretic or pain medication	No	Yes	No	No		No	No	17JUL2020	1
			C4591001 1007 10071046	1	22JUN2020	Oral temperature (°C)	37.1	36.4	36.9		36.4	36.3	36.9		
						Fatigue	N	N	N		N	N	N		
						Headache	N	Mild	N		N	N	Sev	29JUN2020	7
						Chills	N	N	N		N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N		N	N	Mild	29JUN2020	2
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	N	N		N	N	N		
						New or worsened joint pain	N	N	N		N	N	N		
						Use of antipyretic or pain medication	No	No	No		No	No	No		
				2	15JUL2020	Oral temperature (°C)	36.3	36.7	36.6	37.1	36.9				
						Fatigue	N	N	N	N	N				
						Headache	N	Mild	Mild	Mild	N			18JUL2020	3
						Chills	N	N	N	N	N				
						Vomiting	N	N	N	N	N				
						Diarrhea	N	N	N	N	N				

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N				
						New or worsened joint pain	N	N	N	N	N				
						Use of antipyretic or pain medication	No	No	No	No	No				
			C4591001 1007 10071050	1	22JUN2020	Oral temperature (°C)	36.9	37.7	36.1	37.1	36.7	36.7	36.7		
						Fatigue	N	Mild	N	N	N	N	N	23JUN2020	1
						Headache	Mild	Mild	N	N	N	N	N	23JUN2020	2
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	13JUL2020	Oral temperature (°C)	36.9	36.4	36.1	35.7	36.7	36.9	36.4		
						Fatigue	N	Mild	N	N	N	N	N	14JUL2020	1
						Headache	N	Mild	N	N	N	N	N	14JUL2020	1
						Chills	N	Mild	N	N	N	N	N	14JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	14JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Use of antipyretic or pain medication	No	No	Yes	No	No	No	No	15JUL2020	1
			C4591001 1007 10071058	1 24JUN2020	Oral temperature (°C)	36.8	38.6	36.8	36.9	36.6	36.8	36.4	25JUN2020	1
					Fatigue	N	Mild	N	N	N	N	N	25JUN2020	1
					Headache	N	N	Mild	N	Mild	N	N	28JUN2020	3
					Chills	N	Mild	N	N	N	N	N	25JUN2020	1
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	Mild	N	N	N	N	N	25JUN2020	1
					New or worsened joint pain	N	N	N	N	N	N	N		
					Use of antipyretic or pain medication	No	No	Yes	No	Yes	No	No	28JUN2020	3

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	15JUL2020	Oral temperature (°C)	36.9	37.7	37.4	36.6	36.7	36.4	36.9		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	Mild	N	N	N	N	N	16JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	16JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	16JUL2020	1
			C4591001 1007 10071063	1	24JUN2020	Oral temperature (°C)	36.7	36.7	37.4	36.7	36.4	36.3	36.3		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	Mild	N	29JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	15JUL2020	Oral temperature (°C)	36.4	37.6	37.7	36.9	36.4	36.8	36.1		
						Fatigue	N	Mild	N	N	N	N	N	16JUL2020	1
						Headache	N	Mild	N	N	N	N	N	16JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	Mod	N	N	N	N	N	16JUL2020	1
					New or worsened joint pain	N	N	N	N	N	N	N		
					Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071064	1 24JUN2020	Oral temperature (°C)	36.6	37.2	36.7	36.4	36.4	36.6	36.6		
					Fatigue	N	N	N	N	N	N	N		
					Headache	N	N	N	N	N	N	N		
					Chills	N	N	N	N	N	N	N		
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	Mild	N	N	N	N	N	25JUN2020	1
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	15JUL2020	Oral temperature (°C)	36.4	38.8	36.9	36.6	36.4	36.4	36.4	16JUL2020	1
						Fatigue	N	Mild	N	N	N	N	N	16JUL2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	Mod	N	N	N	N	N	16JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	16JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	16JUL2020	1
			C4591001 1007 10071066	1	24JUN2020	Oral temperature (°C)	36.9	37.2	36.9	36.9	36.5	36.6	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	Mild	N	N	N	N	N	25JUN2020	1
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	15JUL2020	Oral temperature (°C)	36.5	37.7	37.1		36.3	36.4			
						Fatigue	N	Mild	N		N	N		16JUL2020	1
						Headache	N	Mild	N		N	N		16JUL2020	1
						Chills	N	Mod	N		N	N		16JUL2020	1
						Vomiting	N	N	N		N	N			
						Diarrhea	N	N	N		N	N			
						New or worsened muscle pain	N	Mod	N		N	N		16JUL2020	1
						New or worsened joint pain	N	Mod	N		N	N		16JUL2020	1
						Use of antipyretic or pain medication	No	Yes	No		No	No		16JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
Placebo	18-55	Placebo	C4591001 1003 10031016	1	09JUN2020	Oral temperature (°C)	36.3	36.5	36.7		36.4		36.7		
						Fatigue	Mild	N	Mild		N		N	11JUN2020	3
						Headache	N	N	N		N		N		
						Chills	N	N	N		N		N		
						Vomiting	N	N	N		N		N		
						Diarrhea	N	N	N		N		N		
						New or worsened muscle pain	N	N	N		N		N		
						New or worsened joint pain	N	N	N		N		N		
Use of antipyretic or pain medication	No	No	No		No		No		No						
Placebo	18-55	Placebo	C4591001 1003 10031016	2	30JUN2020	Oral temperature (°C)	36.6	36.7	36.7	36.7		36.7		36.6	
						Fatigue	Mod	N	N	N		N		N	30JUN2020

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N		N	N		
						Chills	N	N	N	N		N	N		
						Vomiting	N	N	N	N		N	N		
						Diarrhea	N	N	N	N		N	N		
						New or worsened muscle pain	N	N	N	N		N	N		
						New or worsened joint pain	N	N	N	N		N	N		
						Use of antipyretic or pain medication	No	No	No	No		No	No		
			C4591001 1003 10031017	1	11JUN2020	Oral temperature (°C)	36.3	36.3	36.2	36.2	36.2	36.2	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	02JUL2020	Oral temperature (°C)	36.6	36.5	36.4	36.3	36.3	36.6	36.6		
						Fatigue	N	Mild	N	Mild	N	N	N	05JUL2020	3
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031029	1	15JUN2020	Oral temperature (°C)	35.6	36.2	36.2	36.3	36.3	36.7	36.1		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	06JUL2020	Oral temperature (°C)	36.2	36.2	36.9	36.6	36.1	36.7	37.1		
						Fatigue	N	N	N	N	N	N	Mod	13JUL2020	2
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031034	1	17JUN2020	Oral temperature (°C)	36.6	36	36.5	36.1	36.1	36.1			
						Fatigue	N	N	N	N	Mild	Mild	25JUN2020	4	
						Headache	N	N	N	N	Mild	N	22JUN2020	1	
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	No	No	No	No	No			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	08JUL2020	Oral temperature (°C)	35.8	35.9	35.8	36.6	35.8	36.1			
						Fatigue	N	N	N	N	N	N			
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	No	No	No	No	No			
			C4591001 1003 10031050	1	22JUN2020	Oral temperature (°C)	36.3	36.2	35.6	35.6	36.2	36.3	36.1		
						Fatigue	Mod	N	N	N	N	N	N	22JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	13JUL2020	Oral temperature (°C)	36.2		36.1		36.8	36.3	36		
						Fatigue	Mod		N		N	N	N	13JUL2020	1
						Headache	N		N		N	N	N		
						Chills	N		N		N	N	N		
						Vomiting	N		N		N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N		N		N	N	N		
					New or worsened muscle pain	N		N		N	N	N		
					New or worsened joint pain	N		N		N	N	N		
					Use of antipyretic or pain medication	No		No		No	No	No		
			C4591001 1003 10031070	1 24JUN2020	Oral temperature (°C)	36.6		35.8	36.5	36.6	36.5	36.6		
					Fatigue	N		N	N	N	N	N		
					Headache	N		N	N	N	N	N		
					Chills	N		N	N	N	N	N		
					Vomiting	N		N	N	N	N	N		
					Diarrhea	N		N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N		N	N	N	N	N		
						worsened joint pain	N		N	N	N	N	N		
						Use of antipyretic or pain medication	No		No	No	No	No	No		
				2	15JUL2020	Oral temperature (°C)	36.6	36.7	36.4	36.2	36.6	36.8	36.1		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071020	1	10JUN2020	Oral temperature (°C)	36.4		36.6	35.7	36.4	36.6	36.1		
						Fatigue	N		N	N	N	N	N		
						Headache	N		N	Mild	N	N	N	13JUN2020	1
						Chills	N		N	N	N	N	N		
						Vomiting	N		N	N	N	N	N		
						Diarrhea	N		N	N	N	N	N		
						New or worsened muscle pain	N		N	N	N	N	N		
						New or worsened joint pain	N		N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No		No	No	No	No	No		
				2	01JUL2020	Oral temperature (°C)	37.4	37.1	36.6		36.7	36.7	36.9		
						Fatigue	Mod	Mod	N		N	N	N	02JUL2020	2
						Headache	Mild	Mild	N		N	N	N	02JUL2020	2
						Chills	Mild	N	N		N	N	N	01JUL2020	1
						Vomiting	Mild	N	N		N	N	N	01JUL2020	1
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	N	N		N	N	N		
						New or worsened joint pain	N	N	N		N	N	N		
						Use of antipyretic or pain medication	No	Yes	No		No	No	No	02JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1007 10071025	1	17JUN2020	Oral temperature (°C)	35.9	36.4	36.2	36	36.9	36.2	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	Mod	N	N	21JUN2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.4	36.8	36.4	37.1	36.6	36.8	36.7		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071065	1	24JUN2020	Oral temperature (°C)	36.5	36.6	36.6	36.8	37	36.3	36.4		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	15JUL2020	Oral temperature (°C)	36.5	37.3	37.2	37	36.8	36.4	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
BNT162b2	65-85	10 µg	C4591001 1003 10031076	1	29JUN2020	New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
						Oral temperature (°C)	36.3	36.2	36.7	36.4	36.8	36.6	37		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	Mild	N	04JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	20JUL2020	Oral temperature (°C)	36.5	36.6	36.7	36.7	36.5	36.8	36.9		
						Fatigue	N	N	N	N	N	N	N		
						Headache	Mild	Mod	N	N	N	Mild	N	25JUL2020	6
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	21JUL2020	1
			C4591001 1003 10031077	1	01JUL2020	Oral temperature (°C)	37	36.7	36.8	36.2	36.4	36.8	36.8		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	22JUL2020	Oral temperature (°C)	36.6	37	36.5	36.1	36.1	36.6	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031078	1	01JUL2020	Oral temperature (°C)	36.5	36.6	36	36.3	36.4	36.7	37.2		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	22JUL2020	Oral temperature (°C)	36.5	36.5	36.3	36.6	36.6	36.2	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031079	1	01JUL2020	Oral temperature (°C)	35.9	36.3	35.3	35.9	35.8	35.6	35.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	22JUL2020	Oral temperature (°C)	36.2	36.1	35.6	35.4	35.9	35.9	36.2		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031080	1	29JUN2020	Oral temperature (°C)	37.1	36.7		36.8	36.6	36.8	36.9		
						Fatigue	N	N		N	N	N	N		
						Headache	N	N		N	N	N	N		
						Chills	N	N		N	N	N	N		
						Vomiting	N	N		N	N	N	N		
						Diarrhea	N	N		N	N	N	N		
						New or worsened muscle pain	N	N		N	N	N	N		
						New or worsened joint pain	N	N		N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No		No	No	No	No		
				2	20JUL2020	Oral temperature (°C)	36.8	37.2	36.2	36.4	36.7	36.4	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	Mild	N	N	N	N	N	21JUL2020	1
						Chills	N	Mild	N	N	N	N	N	21JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	21JUL2020	1
						New or worsened joint pain	N	Mild	N	N	N	N	N	21JUL2020	1
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	21JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1003 10031087	1	01JUL2020	Oral temperature (°C)	36.2	35.9	35.7	35.7	35.9	35.9	35.9		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	22JUL2020	Oral temperature (°C)	36.2	36.2	36.2	36.2	36.1	36.7	35		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071051	1	29JUN2020	Oral temperature (°C)	36.9	35.7	36.2	36.2	36.6	36.5	35.9		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	20JUL2020	Oral temperature (°C)	36.3	36.8	36.3	36.5	36	36.3	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071057	1	30JUN2020	Oral temperature (°C)	35.7	36.7	36.4	36.7	35.9	36.9	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	22JUL2020	Oral temperature (°C)	36.9	37	36.4	37.1	37.1		36.1		
						Fatigue	N	N	N	N	N		N		
						Headache	Mild	N	N	N	N		N	22JUL2020	1
						Chills	N	N	N	N	N		N		
						Vomiting	N	N	N	N	N		N		
						Diarrhea	N	N	N	N	N		N		
						New or worsened muscle pain	N	N	N	N	N		N		
						New or worsened joint pain	N	N	N	N	N		N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	Yes	No	No	No	No		No	22JUL2020	1
			C4591001 1007 10071071	1	29JUN2020	Oral temperature (°C)	35.8	36.7	36.6	36.8	37.1	36.4	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	20JUL2020	Oral temperature (°C)	36.5	36.6	36.7	36.9	36.3	36.6	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071073	1	30JUN2020	Oral temperature (°C)	36.7	36.8	36.9	36.8	36.8	36.7	36.7		
						Fatigue	N	N	N	N	Mild	N	N	04JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	Mild	N	N	04JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	22JUL2020	Oral temperature (°C)	36.6	36.6	36.6	36.7	36.4	36.5	36.5		
						Fatigue	N	Mild	N	N	N	N	N	23JUL2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	N	N	N	N	N	N		
					New or worsened joint pain	N	N	N	N	N	N	N		
					Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071074	1 30JUN2020	Oral temperature (°C)	35.7	35.7	36.3	36.2	36.4	36.8	36.2		
					Fatigue	N	N	N	N	N	N	N		
					Headache	N	N	N	N	N	N	N		
					Chills	N	N	N	N	N	N	N		
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	20JUL2020	Oral temperature (°C)	35.9	36.8	36.1	36.3	36	36.3	36.3		
						Fatigue	N	Mild	N	N	N	N	N	21JUL2020	1
						Headache	N	Mild	N	N	N	N	N	21JUL2020	1
						Chills	N	Mild	N	N	N	N	N	21JUL2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	21JUL2020	1
			C4591001 1007 10071077	1	30JUN2020	Oral temperature (°C)	36.3	35.2	36.6	36.4	36.7	35.7	35.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	22JUL2020	Oral temperature (°C)		37.3	36.1	36.2	35.1	36.7	35.9		
						Fatigue		N	N	N	N	N	N		
						Headache		N	N	N	N	N	N		
						Chills		N	N	N	N	N	N		
						Vomiting		N	N	N	N	N	N		
						Diarrhea		N	N	N	N	N	N		
						New or worsened muscle pain		N	N	N	N	N	N		
						New or worsened joint pain		N	N	N	N	N	N		
						Use of antipyretic or pain medication		No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
		20 µg	C4591001 1003 10031031	1	15JUN2020	Oral temperature (°C)	35.9	36.5	36.2	36.5	36.6	36.2	36.7		
						Fatigue	N	Mild	Mild	Mild	N	N	N	18JUN2020	3
						Headache	Mild	N	N	N	N	N	N	15JUN2020	1
						Chills	Mild	N	N	N	N	N	N	15JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	Mod	N	N	N	N	17JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	06JUL2020	Oral temperature (°C)	37	36.7	36.7	36.6	36.7	36.5	35.9		
						Fatigue	N	Mild	Mild	N	N	N	N	08JUL2020	2

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	Mild	N	N	N	N	N	07JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031035	1	15JUN2020	Oral temperature (°C)	35.2	36.1		36.5	36.5	36.6	36.2		
						Fatigue	N	N		N	N	N	N		
						Headache	N	N		N	N	N	N		
						Chills	N	N		N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N		N	N	N	N		
						Diarrhea	N	N		N	N	N	N		
						New or worsened muscle pain	N	N		N	N	N	N		
						New or worsened joint pain	N	N		N	N	N	N		
						Use of antipyretic or pain medication	No	No		No	No	No	No		
				2	06JUL2020	Oral temperature (°C)	36.5	37.3	36.5	36.5	36.5	35.9	36.3		
						Fatigue	N	Mod	N	N	N	N	N	07JUL2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031053	1	17JUN2020	Oral temperature (°C)	36.1	36.4	36.7	36.2	35.8	36.6	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.8	37	36.2	36.4	37	36.2	37.4		
						Fatigue	N	Mod	N	N	N	N	N	09JUL2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031054	1	17JUN2020	Oral temperature (°C)	36.7		37.1	36.7	36.8	36.3			
						Fatigue	N		N	N	N	N			
						Headache	N		N	N	N	N			
						Chills	N		N	N	N	N			
						Vomiting	N		N	N	N	N			
						Diarrhea	N		N	N	N	N			
						New or worsened muscle pain	N		N	N	N	N			
						New or worsened joint pain	N		N	N	N	N			
						Use of antipyretic or pain medication	No		No	No	No	No			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	08JUL2020	Oral temperature (°C)	37.3	37.6	37.4	36.7	37.2	36.8	36.9		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031055	1	17JUN2020	Oral temperature (°C)	36.4	36.9	36.5	36.1	36.5	36.7	36.8		
						Fatigue	N	Mild	N	N	N	N	N	18JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	18JUN2020	1
				2	06JUL2020	Oral temperature (°C)	36.2	37.7	36.8	36.8	36.7	36.8	36.6		
						Fatigue	N	Mod	N	N	N	N	N	07JUL2020	1
						Headache	N	Mild	N	N	N	N	N	07JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	N	N	N	N	N	N		
					New or worsened joint pain	N	N	N	N	N	N	N		
					Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	07JUL2020	1
			C4591001 1003 10031063	1 17JUN2020	Oral temperature (°C)	36.2	36.3	36.2	36.2	36.5	36.2	37.1		
					Fatigue	N	N	N	N	N	N	N		
					Headache	N	N	N	N	N	N	N		
					Chills	N	N	N	N	N	N	N		
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.6	37	36.2	36.6	37	36.5	36.8		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071031	1	17JUN2020	Oral temperature (°C)	36.6	36.1	35.9	35.9	35.8	36.1	35.8		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.3	36.1	36.1	35.8	36.3	36.6	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1007 10071032	1	15JUN2020	Oral temperature (°C)	36	36	36.2	36.2	36.1	36	36		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	06JUL2020	Oral temperature (°C)	35.9	36.1	35.9	36	36	36	36		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071035	1	15JUN2020	Oral temperature (°C)	36.2	36.7	36.6	36.7	37.1	36.3	36.6		
						Fatigue	N	Mild	N	N	N	N	N	16JUN2020	1
						Headache	N	Mild	N	N	N	N	N	16JUN2020	1
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	06JUL2020	Oral temperature (°C)		37.9	36.4	36.5	36.8	36.2	36.3		
						Fatigue	Mild	N	N	N	N	N	N	07JUL2020	1
						Headache	Mild	N	N	N	N	Mild	12JUL2020	6	
						Chills	Mild	N	N	N	N	N	07JUL2020	1	
						Vomiting		N	N	N	N	N			
						Diarrhea		N	N	N	N	N			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain		N	N	N	N	N	N		
						New or worsened joint pain		N	N	N	N	N	N		
						Use of antipyretic or pain medication		Yes	No	No	No	No	No	07JUL2020	1
			C4591001 1007 10071038	1	17JUN2020	Oral temperature (°C)	36.8	36.9	36.9	36.8	36.4	36.8	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.4	37.1	36.7	36.7	36.9	36.8	36.7		
						Fatigue	Mild	Mild	N	N	N	N	N	09JUL2020	2
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	09JUL2020	1
						New or worsened joint pain	N	Mild	N	N	N	N	N	09JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071039	1	17JUN2020	Oral temperature (°C)	35.8	36.2	35.7	35.6	36.2	36.3	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	08JUL2020	Oral temperature (°C)	35.9	35.6	35.8	35.7	36.4	36.3	36.2		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071052	1	17JUN2020	Oral temperature (°C)	36.5	36.4	36.6	36.4	36.4	36.6	36.4		
						Fatigue	Mild	N	N	N	N	N	N	17JUN2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	Mod	N	N	Mild	Mild	Mild	24JUN2020	7
						Chills	N	N	Mod	N	N	N	N	19JUN2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	Yes	Yes	23JUN2020	6
				2	08JUL2020	Oral temperature (°C)	36.5	36.9	36.6	36.2	36.4	35.9	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	Mod	Mod	Mod	Mild	N	N	N	11JUL2020	4
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	Yes	Yes	Yes	Yes	No	No	No	11JUL2020	4
		30 µg	C4591001 1003 10031037	1	16JUN2020	Oral temperature (°C)	36.6	37.1		36.8	36.7	36.8	36.6		
						Fatigue	N	N		N	N	N	N		
						Headache	N	N		N	N	N	N		
						Chills	N	N		N	N	N	N		
						Vomiting	N	N		N	N	N	N		
						Diarrhea	N	N		N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N		N	N	N	N		
						worsened joint pain	N	N		N	N	N	N		
						Use of antipyretic or pain medication	No	No		No	No	No	No		
				2	07JUL2020	Oral temperature (°C)	37.1	36.8	36.6	36.7	37.2				
						Fatigue	N	N	N	N	N				
						Headache	N	N	N	N	N				
						Chills	N	N	N	N	N				
						Vomiting	N	N	N	N	N				
						Diarrhea	N	N	N	N	N				
						New or worsened muscle pain	N	N	N	N	N				

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N				
						Use of antipyretic or pain medication	No	No	No	No	No				
			C4591001 1003 10031047	1	16JUN2020	Oral temperature (°C)	36.6	36.8	36.4	36.5	36.3	36.3	36.6		
						Fatigue	N	N	N	N	N	N	Mild	22JUN2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	07JUL2020	Oral temperature (°C)	36.7	38.1	36.9	36.8	37.3	37	36.4	08JUL2020	1
						Fatigue	N	N	Mod	N	N	N	N	09JUL2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	Mod	Mild	N	N	N	N	N	08JUL2020	2
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	08JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1003 10031051	1	18JUN2020	Oral temperature (°C)	36.7	36.6	36.1	36.2	36.2	36.5	36.4		
						Fatigue	N	Mild	N	N	N	N	N	19JUN2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	09JUL2020	Oral temperature (°C)	36.8	37	37	36.8	36.5	36.2	36.7		
						Fatigue	N	Mild	N	N	N	N	N	10JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Headache	N	Mild	N	N	N	N	N	10JUL2020	1
					Chills	N	Mild	Mild	N	N	N	N	11JUL2020	2
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	N	N	N	N	N	N		
					New or worsened joint pain	N	N	N	N	N	N	N		
					Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	10JUL2020	1
			C4591001 1003 10031058	1 18JUN2020	Oral temperature (°C)	36.4	37	36.7	36.1	36.2	36.8	36.5		
					Fatigue	N	N	N	N	N	N	N		
					Headache	N	N	N	N	N	N	N		
					Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	09JUL2020	Oral temperature (°C)	36.3	37	36.6	36.7	36.5	36.3	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031069	1	18JUN2020	Oral temperature (°C)	36.1	36.6	36.2	36.1	35.9	36.5	35.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	09JUL2020	Oral temperature (°C)	35.9	36.6	36.2	36.3	35.7	35.9	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071034	1	15JUN2020	Oral temperature (°C)	35.7	36.4	36.2	35.6	35.8	36.5	36.1		
						Fatigue	N	Mod	N	N	N	N	N	16JUN2020	1
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	06JUL2020	Oral temperature (°C)	35.9	36.9	35.6	35.4	36	36.2	35.9		
						Fatigue	N	Mod	N	N	N	N	N	07JUL2020	1
						Headache	N	Mod	N	N	N	N	N	07JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mod	N	N	N	N	N	07JUL2020	1
						New or worsened joint pain	N	Mod	N	N	N	N	N	07JUL2020	1
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	07JUL2020	1
			C4591001 1007 10071037	1	15JUN2020	Oral temperature (°C)	36.2	36.8	36.2	36.2	37.1	36.5	36.5		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	06JUL2020	Oral temperature (°C)	36.9	36.7	36.6	36.9	36.7	36.6	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071043	1	18JUN2020	Oral temperature (°C)	36.4	36.2	36.6	36.2	36.6	36.2	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	Yes	No	23JUN2020	1
				2	09JUL2020	Oral temperature (°C)	36.1	37	36.4	36.7	36.2	36.7	36.2		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	Mild	N	N	N	N	N	10JUL2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071044	1	18JUN2020	Oral temperature (°C)	36.7	36.8	37.1	36.9	36.8	36.8	36.8		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	09JUL2020	Oral temperature (°C)	37.2	37.1	36.9	36.9	36.9	36.7	36.8		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	10JUL2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1007 10071045	1	18JUN2020	Oral temperature (°C)	36.5	36.4	36.4	36.5	35.9	36.4	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	09JUL2020	Oral temperature (°C)	36.4	36.5	36.7	36.7	36.7	36.6			
						Fatigue	N	Mild	N	N	N	N		10JUL2020	1

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	Mild	N	N	N	N	10JUL2020	1	
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	No	No	No	No	No			
			C4591001 1007 10071049	1	18JUN2020	Oral temperature (°C)	36.3	36.6	36.4	36.3	36.3	36.4	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	19JUN2020	1
				2	09JUL2020	Oral temperature (°C)	36.6	36.4	36.4	36.4	36.6	36.3	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	10JUL2020	1
			C4591001 1007 10071053	1	18JUN2020	Oral temperature (°C)	36.3	36.1	36.5	35.9	36.1	35.8			
						Fatigue	N	N	N	N	N	N			
						Headache	N	N	N	N	N	N			
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	N	N	N	N	N	N			

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	No	No	No	No	No			
				2	09JUL2020	Oral temperature (°C)	36.2	36.8	36.3		36.4	36	36.4		
						Fatigue	N	N	Mild		N	N	N	11JUL2020	1
						Headache	N	N	N		N	N	N		
						Chills	N	N	N		N	N	N		
						Vomiting	N	N	N		N	N	N		
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	N	N		N	N	N		
						New or worsened joint pain	N	N	N		N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
Placebo	65-85	Placebo	C4591001 1003 10031036	1	15JUN2020	Use of antipyretic or pain medication	No	No	No	No	No	No	No		
						Oral temperature (°C)	36.7	36.6	36.5	36.3	36.7	36.3	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
Use of antipyretic or pain medication	No	No	No	No	No	No	No								

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	06JUL2020	Oral temperature (°C)	36.8	36.5	36.6	36.7	36.5	36.4	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031043	1	16JUN2020	Oral temperature (°C)	36.6	36.5	36.7	36.6	36.6	36.3	36.1		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	Mod	N	N	20JUN2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	07JUL2020	Oral temperature (°C)	36.8	36	36.2	36.5	36.4	36.2	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	N	N	N	N	N	N		
					New or worsened joint pain	N	N	N	N	N	N	N		
					Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031046	1 18JUN2020	Oral temperature (°C)	35.5	36.2	36.6	36.4		36.6	36.7		
					Fatigue	Mild	Mild	Mod	Mod		Mod	Mod	26JUN2020	9
					Headache	N	N	N	N		N	N		
					Chills	N	N	N	N		N	N		
					Vomiting	N	N	N	N		N	N		
					Diarrhea	N	N	N	N		N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N		N	N		
						New or worsened joint pain	N	N	N	N		N	N		
						Use of antipyretic or pain medication	No	No	No	No		No	No		
				2	09JUL2020	Oral temperature (°C)	36.4	36.8	36.9	36.7	36.8	36.4	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	Mild	N	N	N	N	N	10JUL2020	1
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031056	1	18JUN2020	Oral temperature (°C)	36.3	36.2	36.5	36.5	36.2	36.4	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	09JUL2020	Oral temperature (°C)	36.5	36.6	36.8	36.3	36.2	36.3	36.3		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
			C4591001 1003 10031067	1	17JUN2020	Oral temperature (°C)	36.3	36.2	36	36.2	36.6	35.7	36		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.6	36.1	36.1	36.3	36.3	36.3	36.1		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1003 10031083	1	01JUL2020	Oral temperature (°C)	36.7	36.8	36.7	36.8	36.4	36.8	37.2		
						Fatigue	Mod	Mod	Mod	Mod	Mod	Mod	N	06JUL2020	6
						Headache	N	Mod	Mod	Mod	Mild	Mod	Mild	11JUL2020	10
						Chills	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	Mild	08JUL2020	2
						New or worsened muscle pain	N	Mod	Sev	N	Mod	Mod	Mod	08JUL2020	7
						New or worsened joint pain	N	N	N	N	N	Mod	N	06JUL2020	1
						Use of antipyretic or pain medication	No	No	No	No	No	No	Yes	07JUL2020	1
				2	22JUL2020	Oral temperature (°C)	36.8	36.8	36.6	36.9	36.7	36.6	36.9		
						Fatigue	N	N	Mod	Mod	Mod	Mod	Mild	30JUL2020	7
						Headache	N	N	Mild	Mod	Mod	Mod	Mild	02AUG2020	10
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	Mod	N	Mod	N	27JUL2020	3
						New or worsened joint pain	N	N	N	Mod	N	Mod	Mod	30JUL2020	6
						Use of antipyretic or pain medication	No	No	No	Yes	Yes	Yes	No	27JUL2020	3
			C4591001 1007 10071042	1	17JUN2020	Oral temperature (°C)		36	36.3	35.9	36.4	36.2	35.9		
						Fatigue		N	N	N	N	N	N		
						Headache		N	N	N	N	N	N		
						Chills		N	N	N	N	N	N		
						Vomiting		N	N	N	N	N	N		
						Diarrhea		N	N	N	N	N	N		
						New or worsened muscle pain		N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain		N	N	N	N	N	N		
						Use of antipyretic or pain medication		No	No	No	No	No	No		
				2	08JUL2020	Oral temperature (°C)	36.2	36.4	35.9	36	36.4	36.5	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071056	1	29JUN2020	Oral temperature (°C)	36.3	36	35.8	35.7	36.4	36.3	36.7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
				2	20JUL2020	Oral temperature (°C)	36.7	36.9	36.6	36.3	36.1	36.3	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1007 10071075	1	30JUN2020	Oral temperature (°C)	35.9	35.8	36.1	36.3	35.4	35.7	35.8		
						Fatigue	N	N	N	N	N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
				2	22JUL2020	Oral temperature (°C)	36.5	35.9	35.8		36.3	36.2	36.4		
						Fatigue	N	N	N		N	N	N		
						Headache	N	N	N		N	N	N		
						Chills	N	N	N		N	N	N		
						Vomiting	N	N	N		N	N	N		

16.2.7.3.1 Listing of Systemic Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Diarrhea	N	N	N		N	N	N		
					New or worsened muscle pain	N	N	N		N	N	N		
					New or worsened joint pain	N	N	N		N	N	N		
					Use of antipyretic or pain medication	No	No	No		No	No	No		

Abbreviations: Dur = duration; Mod = moderate; N = none; Sev = severe.

a. Relative Day (Rel Day) = date of event - date of last vaccination + 1.

b. Stop date is the date the event was last reported.

c. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. If the event continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the event is ongoing at the time of the subsequent vaccination, the end date/day for the event is the date/day that the next vaccine was administered, which was used for the duration calculation.

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16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
BNT162b1	18-55	100 µg	C4591001 1001 10011026	1	18MAY2020	Oral temperature (°C)	38.2	37.3	36.3	36.2	35.9	36.1	36.3	18MAY2020	1
						Fatigue	Mild	Mild	N	N	N	N	N	19MAY2020	2
						Headache	N	N	N	N	N	N	N		
						Chills	Mild	N	N	N	N	N	N	18MAY2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	Mild	N	N	N	N	20MAY2020	1
						New or worsened muscle pain	N	N	N	N	N	N	N		
New or worsened joint pain	N	N	N	N	N	N	N								
Use of antipyretic or pain medication	No	No	No	No	No	No	No								
BNT162b1	18-55	100 µg	C4591001 1001 10011028	1	20MAY2020	Oral temperature (°C)	36.7	37.4	37.1	36.7	37	36.2	36.6		

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Fatigue	Mild	Mod	N	N	N	N	N	21MAY2020	2
						Headache	N	Mod	N	N	N	N	N	21MAY2020	1
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	Mild	N	N	N	23MAY2020	1
						New or worsened muscle pain	Mild	Mild	N	N	N	N	N	21MAY2020	2
						New or worsened joint pain	N	Mild	N	N	N	N	N	21MAY2020	1
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	21MAY2020	1
			C4591001 1001 10011030	1	20MAY2020	Oral temperature (°C)	36.2	38.6	36.5	35.9	36.2	36.1	36.6	21MAY2020	1
						Fatigue	N	Mod	N	N	N	N	N	21MAY2020	1
						Headache	N	Mild	N	N	N	N	N	21MAY2020	1

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Chills	N	Mod	N	N	N	N	N	21MAY2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	Yes	No	No	No	No	22MAY2020	2
			C4591001 1001 10011032	1	20MAY2020	Oral temperature (°C)	36.6	37.8	37.4	36.2		36.2	36.3		
						Fatigue	N	N	N	N		N	N		
						Headache	N	Mild	N	N		N	N	21MAY2020	1
						Chills	N	Mild	N	N		N	N	21MAY2020	1
						Vomiting	N	N	N	N		N	N		

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N	N		N	N		
						New or worsened muscle pain	N	Mild	N	N		N	N	21MAY2020	1
						New or worsened joint pain	N	N	N	N		N	N		
						Use of antipyretic or pain medication	No	No	No	No		No	No		
			C4591001 1001 10011034	1	20MAY2020	Oral temperature (°C)	37.6	37.6	37.5	36.8	36.7	36.6	36.3		
						Fatigue	N	N	N	Mild	Mild	N	N	24MAY2020	2
						Headache	Mod	Mod	Mod	Mild	Mod	N	N	24MAY2020	5
						Chills	Mod	N	Mild	N	N	N	N	22MAY2020	3
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	Mild	N	N	N	N	22MAY2020	1

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	Yes	Yes	No	Yes	No	No	24MAY2020	4
			C4591001 1002 10021023	1	18MAY2020	Oral temperature (°C)	36.7	38	36.5	36.1	35.6	36	36	19MAY2020	1
						Fatigue	Mild	Sev	N	N	N	N	N	19MAY2020	2
						Headache	Mild	N	N	N	N	N	N	18MAY2020	1
						Chills	Mild	Sev	N	N	N	N	N	19MAY2020	2
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mod	N	N	N	N	N	19MAY2020	1

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	Mild	Sev	N	N	N	N	N	19MAY2020	2
						Use of antipyretic or pain medication	Yes	Yes	No	No	No	No	No	19MAY2020	2
			C4591001 1002 10021024	1	18MAY2020	Oral temperature (°C)	36.8	36.7	36.5	37	36.7	36.8	37.2		
						Fatigue	Mod	Sev	Mild	Mild	Mild	Mild	Mild	31MAY2020	14
						Headache	Mod	Sev	Mild	N	N	N	N	20MAY2020	3
						Chills	N	Mild	Mild	N	N	N	N	20MAY2020	2
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	Mild	N	N	Mild	N	N	22MAY2020	4
						New or worsened muscle pain	Mod	Sev	N	N	N	N	N	19MAY2020	2
						New or worsened joint pain	N	Mod	N	N	N	N	N	19MAY2020	1

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
						1	2	3	4	5	6	7		
					Use of antipyretic or pain medication	Yes	Yes	Yes	Yes	Yes	No	No	22MAY2020	5
			C4591001 1002 10021027	1 18MAY2020	Oral temperature (°C)	38.2	38	36.7	36.7	36.7	36.7	36.7	19MAY2020	2
					Fatigue	Mod	Mod	N	N	N	N	N	19MAY2020	2
					Headache	Mild	Mod	N	N	N	N	N	19MAY2020	2
					Chills	Mild	Mild	N	N	N	N	N	19MAY2020	2
					Vomiting	N	N	N	N	N	N	N		
					Diarrhea	N	N	N	N	N	N	N		
					New or worsened muscle pain	N	N	N	N	N	N	N		
					New or worsened joint pain	N	N	N	N	N	N	N		
					Use of antipyretic or pain medication	No	Yes	No	No	No	No	No	19MAY2020	1

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c	
						1	2	3	4	5	6	7			
			C4591001 1002 10021034	1	21MAY2020	Oral temperature (°C)	38.4	38.2	36.7	36.2	36.2	36.2	36.6	22MAY2020	2
					Fatigue	Mild	Mod	Mild	N	N	N	N	23MAY2020	3	
					Headache	N	Mild	N	N	N	N	N	22MAY2020	1	
					Chills	Mod	Mild	N	N	N	N	N	22MAY2020	2	
					Vomiting	N	N	N	N	N	N	N			
					Diarrhea	N	N	N	N	N	N	N			
					New or worsened muscle pain	N	Mild	N	N	N	N	N	22MAY2020	1	
					New or worsened joint pain	N	N	N	N	N	N	N			
					Use of antipyretic or pain medication	Yes	Yes	No	No	No	No	No	22MAY2020	2	
			C4591001 1002 10021035	1	21MAY2020	Oral temperature (°C)	37.7	37.1	36	35.7	36	35.2	36.1		

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Fatigue	N	N	N	N	N	N	N		
						Headache	Mild	N	N	N	N	N	N	21MAY2020	1
						Chills	Mod	N	N	N	N	N	N	21MAY2020	1
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	Mild	N	N	N	N	N	22MAY2020	1
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	Yes	Yes	No	No	No	No	No	22MAY2020	2
			C4591001 1002 10021036	1	21MAY2020	Oral temperature (°C)	37.5	36.9	37.2	37.1	36.9	36.3			
						Fatigue	N	N	N	Mod	N	N		24MAY2020	1
						Headache	N	N	N	N	N	N			

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Chills	N	N	N	N	N	N			
						Vomiting	N	N	N	N	N	N			
						Diarrhea	N	N	N	N	N	N			
						New or worsened muscle pain	Mild	N	N	N	N	N	21MAY2020	1	
						New or worsened joint pain	N	N	N	N	N	N			
						Use of antipyretic or pain medication	No	Yes	No	No	No	No	22MAY2020	1	
			C4591001 1002 10021038	1	21MAY2020	Oral temperature (°C)	36.4	38.2	36.2		36.1	36.1	36.5	22MAY2020	1
						Fatigue	N	Mod	N		N	N	N	22MAY2020	1
						Headache	N	N	N		N	N	N		
						Chills	N	Mild	N		N	N	N	22MAY2020	1
						Vomiting	N	N	N		N	N	N		

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Diarrhea	N	N	N		N	N	N		
						New or worsened muscle pain	N	N	N		N	N	N		
						New or worsened joint pain	N	N	N		N	N	N		
						Use of antipyretic or pain medication	Yes	Yes	No		No	No	No	22MAY2020	2
Placebo	18-55	Placebo	C4591001 1001 10011013	1	18MAY2020	Oral temperature (°C)	36.7	36.3	36.7	36.2	36.4	36.3	36.6		
						Fatigue	Mild	N	N	Mild	N	N	N	21MAY2020	4
						Headache	Mild	Mild	N	Mild	N	N	N	21MAY2020	4
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		
			C4591001 1001 10011021	1	20MAY2020	Oral temperature (°C)	36.8	36.3	36.5	36.5	36.6	36.8	36.6		
						Fatigue	N	N	N	N	N	N	N		
						Headache	Mild	N	N	N	N	Mild	N	25MAY2020	6
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						New or worsened joint pain	N	N	N	N	N	N	N		
						Use of antipyretic or pain medication	No	No	No	No	No	Yes	No	25MAY2020	1
			C4591001 1002 10021041	1	21MAY2020	Oral temperature (°C)	36.6	36.7	36.7	36.6	36.6	36.7	36.5		
						Fatigue	N	N	N	N	N	N	N		
						Headache	N	N	N	N	N	N	N		
						Chills	N	N	N	N	N	N	N		
						Vomiting	N	N	N	N	N	N	N		
						Diarrhea	N	N	N	N	N	N	N		
						New or worsened muscle pain	N	N	N	N	N	N	N		
						New or worsened joint pain	N	N	N	N	N	N	N		

16.2.7.3.1.1 Listing of Systemic Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
							1	2	3	4	5	6	7		
						Use of antipyretic or pain medication	No	No	No	No	No	No	No		

Abbreviations: Dur = duration; Mod = moderate; N = none; Sev = severe.

a. Relative Day (Rel Day) = date of event - date of last vaccination + 1.

b. Stop date is the date the event was last reported.

c. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. If the event continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the event is ongoing at the time of the subsequent vaccination, the end date/day for the event is the date/day that the next vaccine was administered, which was used for the duration calculation.

PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 18SEP2020 (19:41)
(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adce_1004_se_100_p1

16.2.7.3.2 Listing of Severe and Grade 4 Systemic Events – Phase 2

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
18-55	C4591001 1007 10071097	2	20AUG2020	New or worsened muscle pain	N	Sev	Mod	Mod	Mod	Mod	Mod		
	C4591001 1013 10131005	1	28JUL2020	Headache	N	N	N	N	Sev		N	01AUG2020	1
	C4591001 1013 10131013	2	18AUG2020	Headache	N	Sev	Mild	Mild	Mod	Mild	N	23AUG2020	5
	C4591001 1013 10131030	2	18AUG2020	Chills	N	Sev	N	N	N	N	N	19AUG2020	1
	C4591001 1016 10161004	2	19AUG2020	Oral temperature (°C)	36.4	39.6	37.1	36.8	36.4	36.2	35.7	20AUG2020	1
	C4591001 1107 11071010	2	18AUG2020	Headache	Mod	N		Mod	Sev	Mod			
	C4591001 1109 11091020	2	18AUG2020	Headache	Mod	Sev	N	N		N	N	19AUG2020	2
	C4591001 1109 11091027	2	21AUG2020	Fatigue		Sev	Mod	N			N	23AUG2020	2
	C4591001 1127 11271014	2	19AUG2020	Fatigue		Sev	Mod	N	Mild	Mild	N	24AUG2020	5
				Headache		Sev	N	N	N	N	N	20AUG2020	1
				New or worsened muscle pain		Sev	Mod	N	N	N	N	21AUG2020	2

16.2.7.3.2 Listing of Severe and Grade 4 Systemic Events – Phase 2

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c	
					1	2	3	4	5	6	7			
56-85	C4591001 1129 11291006	2	17AUG2020	Fatigue		Sev	Mod	N	N	N	N	19AUG2020	2	
				Chills		Sev	N	N	N	N	N	18AUG2020	1	
	C4591001 1139 11391015	2	21AUG2020	Fatigue	N	Sev	N	N	N	N	N	22AUG2020	1	
	C4591001 1142 11421014	2	19AUG2020	Fatigue	N	Sev		N	N	N	Mild			
	C4591001 1142 11421015	2	18AUG2020	Oral temperature (°C)				39.1		36.9	36.7	36.9	20AUG2020	1
				Headache				Sev		Mild	Mild	Mild		
				Chills				Sev		Mild	N	N	22AUG2020	3
	C4591001 1001 10011084	2	18AUG2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	N	19AUG2020	1
	C4591001 1001 10011093	2	19AUG2020	Fatigue	N	Sev	N	N	N	N	N	N	20AUG2020	1
	C4591001 1109 11091008	2	18AUG2020	Chills	N	Sev	Mild	N	N	N	N	N	20AUG2020	2
C4591001 1142 11421012	2	18AUG2020	Fatigue	N	Sev	N	N	N	N	N	N	19AUG2020	1	
			Headache	N	Sev	Mod	N	N	N	N	N	20AUG2020	2	

16.2.7.3.2 Listing of Severe and Grade 4 Systemic Events – Phase 2

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
<p>Abbreviations: Dur = duration; Mod = moderate; N = none; Sev = severe.</p> <p>a. Relative Day (Rel Day) = date of event - date of last vaccination + 1.</p> <p>b. Stop date is the date the event was last reported.</p> <p>c. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. If the event continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the event is ongoing at the time of the subsequent vaccination, the end date/day for the event is the date/day that the next vaccine was administered, which was used for the duration calculation.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 11SEP2020 (11:50) (Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adce_1004_sevse_p2</p>													

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c	
					1	2	3	4	5	6	7			
16-55	C4591001 1001 10011125	1	04AUG2020	Fatigue	Mod	Mod	Sev	Mild				N	07AUG2020	4
				Headache	Mod	Mod	Sev	Mod				N	07AUG2020	4
				New or worsened muscle pain	N	N	Sev	N				N	06AUG2020	1
				New or worsened joint pain	N	Mild	Sev	N				N	06AUG2020	2
	C4591001 1003 10031160	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	N	28AUG2020	1
	C4591001 1003 10031191	2	02SEP2020	Headache	Mild	Sev	Mild	N	N	Mild	N	N	07SEP2020	6
	C4591001 1005 10051024	2	31AUG2020	Fatigue		Sev	N	N	N			N	01SEP2020	1
	C4591001 1005 10051066	2	02SEP2020	Fatigue	N	Sev	N	N	N	N			03SEP2020	1
				Chills	N	Sev	N	N	N	N			03SEP2020	1
	C4591001 1006 10061024	2	31AUG2020	Fatigue	N	Sev	Mod	N	N	N		N	02SEP2020	2
	C4591001 1006 10061037	2	04SEP2020	Fatigue	N	Sev	N		Mod	Mod		N	09SEP2020	5
	C4591001 1006 10061040	1	14AUG2020	Headache	Mild	Mild	Sev	N	N	N		Mod	21AUG2020	8
	C4591001 1006 10061053	2	09SEP2020	Fatigue	Mod	Sev	Mild	Mild	Mild	Mild		Mild	16SEP2020	8
			Chills	Mod	Sev	Mild	N	N	N		N	11SEP2020	3	
C4591001 1006 10061084	2	10SEP2020	Fatigue	Sev	N						N	Mild	17SEP2020	8
C4591001 1007 10071097	2	20AUG2020	New or worsened muscle pain	N	Sev	Mod	Mod	Mod	Mod		Mod	01SEP2020	12	

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1007 10071111	1	03AUG2020	Chills	N	Sev	N	N		N	N	04AUG2020	1
				New or worsened muscle pain	N	Sev	N	N		N	N	04AUG2020	1
	C4591001 1007 10071130	2	26AUG2020	Chills	N	Sev	N	N	N	N	N	27AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	27AUG2020	1
	C4591001 1007 10071146	2	27AUG2020	New or worsened muscle pain	N	Sev	N		N	N	N	28AUG2020	1
	C4591001 1007 10071157	2	31AUG2020	Fatigue	N	Sev	N	N	N	N	N	01SEP2020	1
				Chills	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1009 10091028	2	31AUG2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1011 10111035	2	03SEP2020	Fatigue	Sev	Sev	Sev	Mild	Mild	N	N	07SEP2020	5
				Headache	N	Sev	Mod	N	Mild	N	N	07SEP2020	4
				Chills	N	Sev	Mod	N	N	N	N	05SEP2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1011 10111129	2	21SEP2020	Headache	Sev	N	N	N	N		N	21SEP2020	1
	C4591001 1012 10121001	1	03AUG2020	Headache	Mild	Sev		N	N	N	N	04AUG2020	2
	C4591001 1013 10131005	1	28JUL2020	Headache	N	N	N	N	Sev		N	01AUG2020	1
	C4591001 1013 10131013	2	18AUG2020	Headache	N	Sev	Mild	Mild	Mod	Mild	N	23AUG2020	5

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16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1013 10131030	2	18AUG2020	Chills	N	Sev	N	N	N	N	N	19AUG2020	1
	C4591001 1013 10131055	2	24AUG2020	New or worsened muscle pain		N	Sev	N	N		N	26AUG2020	1
	C4591001 1013 10131059	2	25AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	27AUG2020	2
	C4591001 1013 10131062	2	24AUG2020	Fatigue	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1013 10131084	2	26AUG2020	Vomiting	N	N	N	N	N	Mod	Sev	01SEP2020	2
	C4591001 1013 10131180	2	03SEP2020	New or worsened muscle pain	N	Sev						06SEP2020	2
				New or worsened joint pain	N	Sev						06SEP2020	2
	C4591001 1015 10151030	1	15AUG2020	Fatigue	N	Sev	Mod	Mild	Mild	Sev	Mod	21AUG2020	6
		2	04SEP2020	Fatigue	N	Sev		Mod	Mod	N		08SEP2020	4
				Headache	N	Sev		Mod	Mod	N		08SEP2020	4
				New or worsened muscle pain	N	Sev		Mod	N	N		07SEP2020	3
	C4591001 1015 10151035	2	04SEP2020	Fatigue		Sev	N	N	N	N	N	05SEP2020	1
				New or worsened muscle pain		Sev	N	N	N	N	N	05SEP2020	1
				New or worsened joint pain		Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1016 10161004	2	19AUG2020	Oral temperature (°C)	36.4	39.6	37.1	36.8	36.4	36.2	35.7	20AUG2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1016 10161078	2	28AUG2020	Headache	N	Sev	N	N	N	N	N	29AUG2020	1
				Chills	N	Sev	N	N	N	N	N	29AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	29AUG2020	1
	C4591001 1018 10181013	1	30JUL2020	Fatigue	N	N	N	N	N	Sev	N	04AUG2020	1
	C4591001 1018 10181055	2	25AUG2020	Fatigue	N	Sev	Mod	N	Mild	Mild	Mild	31AUG2020	6
				New or worsened muscle pain	N	Sev	Mild	N	Mild	Mild	N	30AUG2020	5
	C4591001 1018 10181089	2	27AUG2020	New or worsened joint pain	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1018 10181151	2	03SEP2020	Fatigue	Sev	Mild	N	N	N		N	04SEP2020	2
	C4591001 1042 10421070	2	31AUG2020	Fatigue	Mod	Sev	Mod	N	N	N	N	02SEP2020	3
	C4591001 1042 10421105	2	02SEP2020	Oral temperature (°C)	36.7	38.9	36.7	36.7	36.8	36.6	36.1	03SEP2020	1
	C4591001 1052 10521017	1	21AUG2020	Diarrhea	N	Mild	Mod	Mod	Mod	Sev	Mod	27AUG2020	6
	C4591001 1052 10521036	1	26AUG2020	Fatigue	Mod	Sev	N	N	N		N	27AUG2020	2
	C4591001 1055 10551003	2	27AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	29AUG2020	2
	C4591001 1057 10571028	2	08SEP2020	Fatigue	N	Sev	N	N	N	N	N	09SEP2020	1
	C4591001 1066 10661027	1	13AUG2020	Fatigue	Mild	N			Sev	Mod	Mod	20AUG2020	8

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16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c	
					1	2	3	4	5	6	7			
	C4591001 1071 10711019	2	02SEP2020	Fatigue	N	Sev				N	N	N	03SEP2020	1
	C4591001 1071 10711039	2	04SEP2020	Headache	N	N	Mod	Sev		Mild	Mild		21SEP2020	16
	C4591001 1071 10711065	2	09SEP2020	Headache	Sev	Sev	N	N	N	N	Mild		17SEP2020	9
	C4591001 1073 10731021	1	31JUL2020	Fatigue	Mild	Sev	Mod	N		N	N		02AUG2020	3
		2	24AUG2020	Fatigue	N	Sev	Mod	N	N	N	N		26AUG2020	2
	C4591001 1073 10731064	2	01SEP2020	Fatigue	Mod	Mod	Mod	Sev	N	N	N		04SEP2020	4
				Headache	N	Mod	N	Sev	N	N	N		04SEP2020	3
	C4591001 1073 10731083	2	02SEP2020	Fatigue	Mod	Sev	N	N	N		N		03SEP2020	2
				Chills	N	Sev	N	N	N		N		03SEP2020	1
	C4591001 1077 10771013	2	31AUG2020	Fatigue	N	Sev	N	Mod		Mod	N		05SEP2020	5
				Chills	N	Sev	N	N		N	N		01SEP2020	1
	C4591001 1079 10791039	2	25AUG2020	Headache	N	Mild	N	N	Mod	Sev			02SEP2020	8
	C4591001 1079 10791040	2	24AUG2020	Headache						Sev		N	28AUG2020	1
	C4591001 1079 10791097	2	31AUG2020	Chills		Sev	N	N	N		N		01SEP2020	1
	C4591001 1079 10791112	1	12AUG2020	Headache	Mild	Sev	N	N	N	N	N		13AUG2020	2
	C4591001 1079 10791115	1	12AUG2020	Headache	Mild	Mild		Mild	Sev	Mod	Mild		18AUG2020	7

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16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1079 10791127	2	03SEP2020	Oral temperature (°C)	36.8	39	37.2	36.9	36.8	36.6	36.6	04SEP2020	1
	C4591001 1080 10801009	2	03SEP2020	Headache		Sev	Mod	N			N	05SEP2020	2
	C4591001 1081 10811033	2	03SEP2020	Fatigue	N	Sev	N	N	N	N		04SEP2020	1
	C4591001 1082 10821036	1	04AUG2020	Headache	Mod	N	Mild	N	N	N	Sev	11AUG2020	8
		2	25AUG2020	Headache	N	Sev	Sev	N	N	N	Mod	31AUG2020	6
	C4591001 1083 10831020	2	24AUG2020	Fatigue	N	Sev	N	N		N	N	25AUG2020	1
	C4591001 1083 10831060	1	06AUG2020	Oral temperature (°C)	36.5	37.8	37.8	38.6	38.6	38.9	38.7		
	C4591001 1084 10841068	2	28AUG2020	Chills	N	Sev	N					29AUG2020	1
	C4591001 1084 10841091	2	28AUG2020	Fatigue	N	Sev	N	N	N	N	N	29AUG2020	1
	C4591001 1084 10841102	2	31AUG2020	Headache	N	Sev	Mod	Mod	Mild	N	N	04SEP2020	4
	C4591001 1084 10841118	1	10AUG2020	Fatigue	N	Sev	N	N	N	N	N	11AUG2020	1
	C4591001 1084 10841146	2	02SEP2020	Fatigue	N	Sev	Mild	N	N	N	N	04SEP2020	2
	C4591001 1084 10841187	1	14AUG2020	Fatigue	Mild	Sev	Mild	N		N	N	16AUG2020	3
	C4591001 1084 10841188	1	14AUG2020	Headache	N	N	Mod	Sev	N	N	N	17AUG2020	2
		2	04SEP2020	Headache	N	N	N	N	N	N	Sev	10SEP2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1085 10851018	1	01AUG2020	Diarrhea	N	N	N	Mod	N	Mod	Sev	07AUG2020	4
	C4591001 1085 10851075	2	29AUG2020	Fatigue	Sev	Mod	Mild	N	N	N	N	31AUG2020	3
	C4591001 1087 10871045	1	10AUG2020	Fatigue	Sev	Sev	Sev	Sev	Sev	Sev	Sev	24AUG2020	15
				New or worsened muscle pain	N	N	N	N	Mod	Mod	Sev	24AUG2020	11
		2	31AUG2020	Fatigue	Mild	Mod		Sev	Sev	Sev	Sev		
				Headache	Mild	Mod		Mod	Mod	Mod	Sev		
	C4591001 1088 10881010	1	12AUG2020	Chills	N	Mild	Sev	N	N	N	N	14AUG2020	2
				Diarrhea	N	Mild	Sev	Sev	Mild	Mild	N	17AUG2020	5
	C4591001 1088 10881012	2	04SEP2020	Fatigue	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1089 10891025	2	20AUG2020	Headache	N	Sev	Mod	Mod	Mild		Mild	26AUG2020	6
	C4591001 1089 10891054	1	04AUG2020	Fatigue	N	Mild	Mod		Sev		Sev	14AUG2020	10
	C4591001 1089 10891078	2	27AUG2020	Fatigue		Sev	N	N	N	N	N	28AUG2020	1
				Diarrhea		N	Sev	N	N	N	N	29AUG2020	1
	C4591001 1089 10891082	1	07AUG2020	Headache	N	Sev				N	N	08AUG2020	1
	C4591001 1089 10891103	2	31AUG2020	New or worsened joint pain	N	N	Sev	N			N	02SEP2020	1
	C4591001 1090 10901015	2	24AUG2020	Fatigue	N	Sev	N	N		N	N	25AUG2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1090 10901022	2	28AUG2020	Headache		Sev	Mod	N	N	N	N	30AUG2020	2
	C4591001 1090 10901043	2	24AUG2020	Headache	Mild	Sev	N	N		N	Mild	30AUG2020	7
				Chills	N	Sev	N	N		N	N	25AUG2020	1
	C4591001 1090 10901045	2	24AUG2020	Headache	N	Sev	N	Mild	N	N		27AUG2020	3
				Chills	N	Sev	Mild	N	N	N		26AUG2020	2
	C4591001 1090 10901050	2	24AUG2020	Fatigue	N	Sev		N	N	N	N	25AUG2020	1
				Headache	N	Sev		N	N	N	N	25AUG2020	1
				Chills	N	Sev		N	N	N	N	25AUG2020	1
				New or worsened muscle pain	N	Sev		N	N	N	N	25AUG2020	1
	C4591001 1090 10901095	1	07AUG2020	Oral temperature (°C)	36.7	37.6	39.3	36.7	36.7	37.2	36.7	09AUG2020	1
		2	28AUG2020	Oral temperature (°C)	37	39.7	38	37.3	37.1	36.4	37	30AUG2020	2
	C4591001 1090 10901104	1	07AUG2020	Fatigue	N	Mild	Sev	Mod	Mild	N	N	11AUG2020	4
				New or worsened muscle pain	N	Mod	Sev	Mod	N	N	N	10AUG2020	3
	C4591001 1091 10911037	1	04AUG2020	Fatigue	N	Sev	N	N	N	N	N	05AUG2020	1
	C4591001 1091 10911051	2	26AUG2020	Oral temperature (°C)	38.4	38.9	36.6	36.5	36.6	36.7		27AUG2020	2
	C4591001 1091 10911107	2	02SEP2020	Fatigue	Mod	Sev	N	N	N	N	N	03SEP2020	2
				Headache	Mod	Sev	N	N	N	N	N	03SEP2020	2

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
				Chills	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1091 10911121	2	01SEP2020	Headache		Sev	N	N	N	Mild	N	06SEP2020	5
	C4591001 1094 10941016	1	14AUG2020	Fatigue	Sev	Mild	N	N		N	Sev	27AUG2020	14
	C4591001 1095 10951093	2	28AUG2020	Fatigue	Mod	Sev	Mod	Mod	Mod	N	N	01SEP2020	5
	C4591001 1107 11071010	2	18AUG2020	Headache	Mod	N		Mod	Sev	Mod		23AUG2020	6
	C4591001 1107 11071055	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1107 11071065	1	06AUG2020	Oral temperature (°C)	37.1	37.3	39.6	37.1	37.2	38.2	37.8	11AUG2020	4
	C4591001 1107 11071087	2	01SEP2020	Headache	Mod	Sev	Mild	N	N	N	N	03SEP2020	3
	C4591001 1109 11091020	2	18AUG2020	Headache	Mod	Sev	N	N		N	N	19AUG2020	2
	C4591001 1109 11091027	2	21AUG2020	Fatigue		Sev	Mod	N			N	23AUG2020	2
	C4591001 1109 11091060	2	20AUG2020	Oral temperature (°C)		38.9	37	38.6	38.3	38.4		26AUG2020	6
	C4591001 1109 11091102	2	21AUG2020	Fatigue	N	Sev	N	N	N	N	N	22AUG2020	1
				Headache	N	Sev	N	N	N	N	N	22AUG2020	1
				Vomiting	N	Sev	N	N	N	Mild	N	26AUG2020	5
				New or worsened joint pain	N	Sev	N	N	N	N	N	22AUG2020	1
	C4591001 1109 11091178	2	28AUG2020	Fatigue		Sev	N	N		Mod	N	02SEP2020	5

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1109 11091228	2	03SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1109 11091246	2	08SEP2020	New or worsened muscle pain					Sev		Mod	15SEP2020	4
	C4591001 1109 11091258	2	08SEP2020	Headache		Sev	N	Mod	Mod		N	12SEP2020	4
	C4591001 1109 11091267	1	16AUG2020	Fatigue	Mod	Mod	Sev	Mod	Mod			21AUG2020	6
		2	08SEP2020	Fatigue	Sev	N	N	N	N	Mod	N	13SEP2020	6
	C4591001 1110 11101027	2	24AUG2020	Oral temperature (°C)		39.4	38.1		37.9	37.2	37.2	26AUG2020	2
				Fatigue		Sev	Mod		Mod	N	N	28AUG2020	4
				New or worsened muscle pain		Sev	Mod		N	N	N	26AUG2020	2
				New or worsened joint pain		Sev	Mod		N	N	N	26AUG2020	2
	C4591001 1110 11101033	2	25AUG2020	Fatigue	Mild	Sev		N	N	N	N	26AUG2020	2
	C4591001 1110 11101095	2	03SEP2020	Chills	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1111 11111072	2	31AUG2020	New or worsened joint pain	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1111 11111115	2	04SEP2020	Fatigue	Mild	N	N	Mod	Sev	Mod	Mod	10SEP2020	7
	C4591001 1112 11121045	1	03AUG2020	Oral temperature (°C)	36.9	39	37	37.1	36.9	36.8	36.6	04AUG2020	1
	C4591001 1112 11121180	2	16SEP2020	New or worsened joint pain		Sev	Sev	Mild	Mild	Mild	Mild	22SEP2020	6

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1120 11201039	2	24AUG2020	Fatigue	Mod	Sev	Mild	Mild	N	N	N	27AUG2020	4
	C4591001 1120 11201082	2	25AUG2020	Fatigue	Mild	Mild	N	Mod	Mild	Mod	Sev	02SEP2020	9
	C4591001 1120 11201103	2	25AUG2020	Fatigue	N	Sev	N	N	N	N	N	26AUG2020	1
	C4591001 1120 11201148	1	12AUG2020	Fatigue	Mild	Mod	Mild	Sev	Mild	Mod	Mild	19AUG2020	8
		2	31AUG2020	Headache	N	Sev	N	Mild	N		N	03SEP2020	3
	C4591001 1120 11201172	1	13AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	15AUG2020	2
	C4591001 1120 11201244	2	09SEP2020	Headache		Sev	N	N	N	N	N	10SEP2020	1
	C4591001 1120 11201250	2	11SEP2020	Headache	N	Sev	N	N	N	N	N	12SEP2020	1
				New or worsened joint pain	N	Sev	N	N	N	Mod	Mild		
	C4591001 1120 11201278	2	02OCT2020	Chills		Sev	N	N	N	N	N	03OCT2020	1
	C4591001 1120 11201281	2	12OCT2020	New or worsened joint pain	N	N	Sev	N	N	N	N	14OCT2020	1
	C4591001 1123 11231090	2	03SEP2020	Fatigue	N	Sev	N		N	N	N	04SEP2020	1
	C4591001 1124 11241019	1	12AUG2020	Fatigue	N	Sev	N	N	N	Mod	N	17AUG2020	5
	C4591001 1125 11251024	2	01SEP2020	Fatigue	N	Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1127 11271014	2	19AUG2020	Fatigue		Sev	Mod	N	Mild	Mild	N	24AUG2020	5

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
				Headache		Sev	N	N	N	N	N	20AUG2020	1
				New or worsened muscle pain		Sev	Mod	N	N	N	N	21AUG2020	2
	C4591001 1127 11271022	1	30JUL2020	Fatigue		Mild	Mod		Sev	Mod	Mild	16AUG2020	17
	C4591001 1127 11271032	1	31JUL2020	Headache		Sev	Mod		Sev	Mod	Mild	16AUG2020	17
				Fatigue	N	Sev	Mild	N	N	N	N	02AUG2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	01AUG2020	1
		2	19AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	21AUG2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	20AUG2020	1
	C4591001 1128 11281021	2	21AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	23AUG2020	2
				Chills	N	Sev	N	N	N	N	N	22AUG2020	1
	C4591001 1128 11281024	2	20AUG2020	Fatigue	N	Sev	N	N	N	N	N	21AUG2020	1
				Headache	N	Sev	N	N	N	N	N	21AUG2020	1
	C4591001 1128 11281054	2	26AUG2020	Fatigue	Mod	Sev	N	Mod	Mod	Mod	Mod		
	C4591001 1128 11281119	2	03SEP2020	New or worsened muscle pain	Mod	Sev	N	N		N	N	04SEP2020	2
				New or worsened joint pain	Mild	Sev	N	N		N	N	04SEP2020	2
	C4591001 1129 11291006	2	17AUG2020	Fatigue		Sev	Mod	N	N	N	N	19AUG2020	2
				Chills		Sev	N	N	N	N	N	18AUG2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1129 11291061	1	07AUG2020	Fatigue	Mod	Sev	Mod	Mild		N	N	10AUG2020	4
	C4591001 1129 11291089	1	11AUG2020	Fatigue	N	Mod	Sev		N	Mild	N	16AUG2020	5
				Headache	N	N	Sev		N	Mild	N	16AUG2020	4
	C4591001 1133 11331051	2	24AUG2020	Oral temperature (°C)	37.1	39.4	37.4	37.2	37.2	37.3	37.2	25AUG2020	1
				Headache	N	Sev	N	N	N	N	N	25AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1133 11331152	2	09SEP2020	Diarrhea	N	Sev		N	N	N		10SEP2020	1
	C4591001 1133 11331180	1	14AUG2020	Oral temperature (°C)	32.2	39.2	33.3	37.3	37.4	37.5		15AUG2020	1
		2	04SEP2020	Oral temperature (°C)	37.3	39	38.8	38.8	37.3	38	37.4	09SEP2020	5
	C4591001 1135 11351036	1	05AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	07AUG2020	2
	C4591001 1135 11351088	2	28AUG2020	Fatigue	Mild	Sev	N	N	N	N	N	29AUG2020	2
	C4591001 1135 11351114	2	01SEP2020	Fatigue	Mod	Sev		N	Mild	N	N	05SEP2020	5
				Chills	N	Sev		N	N	N	N	02SEP2020	1
				New or worsened muscle pain	N	Sev		N	N	N	N	02SEP2020	1
	C4591001 1139 11391015	2	21AUG2020	Fatigue	N	Sev	N	N	N	N	N	22AUG2020	1
	C4591001 1139 11391062	2	26AUG2020	Fatigue	N	Sev	N	N	N	Mild	N	31AUG2020	5

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1139 11391070	1	07AUG2020	Fatigue	N	Sev	N	N	N	N	N	08AUG2020	1
	C4591001 1140 11401022	1	03AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	05AUG2020	2
				New or worsened muscle pain	Mild	Sev	Mod	N	N	N	N	05AUG2020	3
		2	25AUG2020	Oral temperature (°C)	37.8	39.8	37.3	37.1	37.2	37.2	37.1	26AUG2020	1
				Fatigue	N	Sev	Mod	N	N	N	N	27AUG2020	2
				Chills	N	Sev	N	N	N	N	N	26AUG2020	1
				New or worsened muscle pain	Mild	Sev	N	Mild	N	N	N	28AUG2020	4
	C4591001 1140 11401031	2	24AUG2020	Oral temperature (°C)	37.1	39	36.6	36.6	36.1	36.4	36.1	25AUG2020	1
				Headache	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1140 11401037	2	27AUG2020	Oral temperature (°C)	36.6	39.4	36.6	36.2		35.9	35.9	28AUG2020	1
				Fatigue	Mild	Sev	Mod	N		N	N	29AUG2020	3
	C4591001 1140 11401045	2	24AUG2020	Headache	Sev	Mild	N	N	N	N	Mild	30AUG2020	7
	C4591001 1140 11401049	1	05AUG2020	Headache	N	N	N	N	N	N	Sev	12AUG2020	2
	C4591001 1140 11401065	1	06AUG2020	New or worsened muscle pain	N	Sev	N	N	N		N	07AUG2020	1
		2	28AUG2020	New or worsened muscle pain	N	Sev	Mild	N	N	N		30AUG2020	2
				New or worsened joint pain	N	Sev	N	N	N	N		29AUG2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c	
					1	2	3	4	5	6	7			
	C4591001 1141 11411026	2	24AUG2020	Fatigue		Sev	N	N	N	N	N	25AUG2020	1	
				Chills		Sev	N	N	N	N	N	25AUG2020	1	
				New or worsened muscle pain		Sev	N	N	N	N	N	25AUG2020	1	
				New or worsened joint pain		Sev	N	N	N	N	N	25AUG2020	1	
	C4591001 1141 11411057	2	01SEP2020	Fatigue		Sev	Mild	N		N	N	03SEP2020	2	
	C4591001 1141 11411081	1	14AUG2020	Fatigue	N	Sev	N	N	N	N	N	15AUG2020	1	
	C4591001 1142 11421014	2	19AUG2020	Fatigue	N	Sev		N	N	N	Mild	26AUG2020	7	
	C4591001 1142 11421015	2	18AUG2020	Oral temperature (°C)				39.1		36.9	36.7	36.9	20AUG2020	1
				Headache				Sev		Mild	Mild	Mild		
				Chills				Sev		Mild	N	N	22AUG2020	3
	C4591001 1142 11421050	2	28AUG2020	Headache	N	Sev	Mild			N			30AUG2020	2
				Chills	N	Sev	N			N			29AUG2020	1
				New or worsened muscle pain	N	Sev	N			N			29AUG2020	1
	C4591001 1142 11421081	2	02SEP2020	Fatigue	N		Sev	N		N	N		04SEP2020	1
	C4591001 1145 11451010	2	02SEP2020	Fatigue	N	Sev	Mild	N	N	N			04SEP2020	2
	C4591001 1146 11461043	2	09SEP2020	Fatigue	Sev	Mild	N	N	N	N			10SEP2020	2

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1147 11471013	2	25AUG2020	Headache	N	N		Sev	Mod	Mild	N	30AUG2020	3
				Chills	N	N		Sev	Mod	N	N	29AUG2020	2
	C4591001 1147 11471019	2	24AUG2020	Fatigue	N	Sev	N	N	N	N	N	25AUG2020	1
				Headache	N	Sev	N	N	N	N	N	25AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	25AUG2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1149 11491016	1	07AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	09AUG2020	2
	C4591001 1149 11491049	2	01SEP2020	Oral temperature (°C)	36.6	39.4	37.9	37.3	37.1	37	37.2	02SEP2020	1
				Headache	N	Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1149 11491063	2	02SEP2020	Oral temperature (°C)	37.3	39.3	37.7	37.7	37.7	37	36.8	03SEP2020	1
	C4591001 1152 11521029	2	02SEP2020	Headache	N	Sev	Mod	Mild	N	N	N	05SEP2020	3
	C4591001 1152 11521072	2	01SEP2020	Diarrhea	N	N	Sev	Mild		N	N	04SEP2020	2
	C4591001 1152 11521076	2	03SEP2020	Fatigue	Mild	Sev	N	N	N	N	N	04SEP2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1157 11571006	2	04SEP2020	Fatigue		Sev	Mild	Mild	Mild	N	N	08SEP2020	4

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
				Chills		Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1157 11571040	2	09SEP2020	Chills	N	Sev	N	N	N	N	N	10SEP2020	1
	C4591001 1162 11621044	1	06AUG2020	Oral temperature (°C)			36.1			40	37.6	11AUG2020	1
				Fatigue			N			Sev	Sev	13AUG2020	3
				Headache			N			Sev	Sev	13AUG2020	3
				Chills			Mild			Sev	Mod	13AUG2020	6
				New or worsened muscle pain			N			Sev	N	11AUG2020	1
	C4591001 1162 11621080	2	02SEP2020	Headache	N	Sev	Mod	N	N	N		04SEP2020	2
				Chills	N	Sev	Mod	N	N	N		04SEP2020	2
	C4591001 1162 11621103	1	13AUG2020	Headache	Sev	Mild	Mod	Mild	Mild	N	N	17AUG2020	5
	C4591001 1162 11621110	2	02SEP2020	Fatigue		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1162 11621115	2	01SEP2020	Headache			N	N	Sev			05SEP2020	1
	C4591001 1163 11631036	2	25AUG2020	Fatigue		N		Sev				03SEP2020	7
				Headache		N		Sev				03SEP2020	7
				Chills		N		Sev				03SEP2020	7
				Vomiting		N		Sev				03SEP2020	7
				Diarrhea		N		Sev				03SEP2020	7
				New or worsened muscle pain		N		Sev				03SEP2020	7

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c	
					1	2	3	4	5	6	7			
				New or worsened joint pain		N		Sev					03SEP2020	7
	C4591001 1163 11631060	1	07AUG2020	Fatigue	N	N	N	N		Sev	N		12AUG2020	1
	C4591001 1163 11631087	2	01SEP2020	Fatigue				Sev	Mild	N	N		05SEP2020	2
	C4591001 1167 11671001	2	02SEP2020	Oral temperature (°C)		39.6	36.8	36.8	36.8	36.8	36.9		03SEP2020	1
				Fatigue		Sev	N	N	N	N	N		03SEP2020	1
				Chills		Sev	N	N	N	N	N		03SEP2020	1
				New or worsened muscle pain		Sev	N	N	N	N	N		03SEP2020	1
				New or worsened joint pain		Sev	N	N	N	N	N		03SEP2020	1
	C4591001 1167 11671002	2	04SEP2020	New or worsened muscle pain	N	Mod	Sev	N		N	N		06SEP2020	2
	C4591001 1167 11671006	2	02SEP2020	Fatigue	N	Sev	N	N	N	N	N		03SEP2020	1
	C4591001 1170 11701002	2	02SEP2020	Oral temperature (°C)	37.8	41.2	37.2	36.7	37.1	36.9	36.7		03SEP2020	1
	C4591001 1171 11711020	2	04SEP2020	Fatigue		Sev	Mild	N	N	N	N		06SEP2020	2
	C4591001 1171 11711027	1	14AUG2020	Chills	N	Sev	N	N	N	N	N		15AUG2020	1
	C4591001 1177 11771039	2	09SEP2020	Chills	N	Sev	N	N	N	N	N		10SEP2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N		10SEP2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1223 12231027	1	28AUG2020	Fatigue	Mild	Sev	Mild	N	N	N	N	30AUG2020	3
	C4591001 1223 12231057	1	01SEP2020	Headache	N	Sev	Mild	N	N	N	N	03SEP2020	2
	C4591001 1223 12231074	2	23SEP2020	Fatigue		Sev	N		N	N		24SEP2020	1
	C4591001 1224 12241005	1	12AUG2020	Headache	N	Mod	Sev	N	N	N	N	14AUG2020	2
	C4591001 1226 12261001	2	25AUG2020	New or worsened muscle pain	Mod	Sev		N	N	N		26AUG2020	2
	C4591001 1226 12261008	1	05AUG2020	Headache	N	Sev	N	N	N	N	N	06AUG2020	1
		2	24AUG2020	Headache		Sev	N	N	N	Mild	N	29AUG2020	5
	C4591001 1226 12261019	1	06AUG2020	Fatigue	N	N	N	N	Sev	N	N	10AUG2020	1
	C4591001 1226 12261025	2	25AUG2020	Fatigue		Mild	Mod	Sev	Mild	Mod	N	30AUG2020	5
				Headache		Mild	N	Mod	Mild	Sev	N	30AUG2020	5
				New or worsened muscle pain		N	N	N	N	Sev	N	30AUG2020	1
	C4591001 1226 12261055	1	10AUG2020	Fatigue	N	N	Mild	N	Sev	Mod		16AUG2020	5
	C4591001 1226 12261066	1	10AUG2020	Headache	N	Mod	Sev	N	N	N	N	12AUG2020	2
	C4591001 1226 12261072	1	11AUG2020	New or worsened muscle pain	N	N	Sev	N	N	N	N	13AUG2020	1
	C4591001 1226 12261089	1	11AUG2020	Headache	Sev	Mild	Mild	N	Mild	N	N	15AUG2020	5

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1226 12261096	1	11AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	13AUG2020	2
				Headache	N	Sev	Mod	N	N	N	N	13AUG2020	2
				New or worsened muscle pain	N	Sev	Mild	N	N	N	N	13AUG2020	2
				New or worsened joint pain	N	Sev	Mild	Mild	N	N	N	14AUG2020	3
		2	01SEP2020	Fatigue	N	Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1226 12261104	1	11AUG2020	Headache	Mod	Sev	Mod	Mild	Mild	N	N	15AUG2020	5
	C4591001 1226 12261106	2	01SEP2020	Fatigue	N	Sev		Mild	N			04SEP2020	3
				Headache	N	Sev		Mild	N			04SEP2020	3
				New or worsened muscle pain	N	Sev		N	N			02SEP2020	1
				New or worsened joint pain	N	Sev		N	N			02SEP2020	1
	C4591001 1226 12261124	2	04SEP2020	Fatigue	N	Sev	N	N	N	N		05SEP2020	1
	C4591001 1226 12261154	1	13AUG2020	Fatigue	Sev	Sev	Mild	N	N	N		15AUG2020	3
		2	16SEP2020	Headache			Sev	Mild	Mod	N	N	20SEP2020	3
	C4591001 1226 12261156	2	03SEP2020	Fatigue	N	Mod	Mod	Sev	N	N	N	06SEP2020	3
				New or worsened joint pain	N	Mod	Mild	Sev	Mild	Mod	N	08SEP2020	5
	C4591001 1226 12261208	2	08SEP2020	Headache	Sev	Mild	N	Mild	N	N	N	11SEP2020	4

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16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1226 12261215	1	17AUG2020	Headache	N	Sev		N	Mild		N	21AUG2020	4
	C4591001 1226 12261232	2	09SEP2020	Fatigue	N	Sev	Mild	N	N	N	N	11SEP2020	2
	C4591001 1226 12261243	1	18AUG2020	Headache	N	N	Sev	N	N	N	N	20AUG2020	1
	C4591001 1226 12261248	2	07SEP2020	Fatigue	Mild	Sev	Mild				N	09SEP2020	3
	C4591001 1229 12291011	2	14OCT2020	Headache		Sev	Mod	Mod	N	N	N	17OCT2020	3
	C4591001 1229 12291016	1	25SEP2020	Headache			N	Mod	Sev	Mild	Mod	01OCT2020	4
	C4591001 1229 12291024	1	28SEP2020	Vomiting	N	Mod	Sev	N	N	N	N	30SEP2020	2
				Diarrhea	N	Sev	Mod	Mild	N	N	N	01OCT2020	3
	C4591001 1229 12291029	1	28SEP2020	Oral temperature (°C)		39.7	33.2	35.2	35.4	35.4	35.4	29SEP2020	1
	C4591001 1229 12291037	1	28SEP2020	Oral temperature (°C)			40.7	42.3	39.6		34.2	02OCT2020	3
	C4591001 1229 12291042†	2	20OCT2020	Headache	Mod	Sev	N	N	N	N	N	21OCT2020	2
	C4591001 1229 12291046	2	20OCT2020	Fatigue	N	Sev	Mild		N	N	N	22OCT2020	2
	C4591001 1229 12291047	1	29SEP2020	New or worsened muscle pain	Sev	Mod		N	N	N	N	30SEP2020	2
	C4591001 1229 12291057	1	30SEP2020	Headache	N	N	N	Sev	Mild	N	N	04OCT2020	2
	C4591001 1229 12291065	1	30SEP2020	Chills	Mod	Mild	Mild	Mod	Sev	N	N	04OCT2020	5

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
		2	21OCT2020	Fatigue	Mild	N	Mod	N	N	Sev	N	26OCT2020	6
				New or worsened muscle pain	N	Mild	N	N	N	Sev	Mod		
	C4591001 1229 12291082	1	01OCT2020	Fatigue	Mild	Sev		N	N	N		02OCT2020	2
				New or worsened muscle pain	Sev	Mod		N	N	N		02OCT2020	2
	C4591001 1229 12291100	2	26OCT2020	Headache	Mod		Mild	Mild	Mild	Sev			
	C4591001 1229 12291105	2	26OCT2020	Fatigue	Sev	Sev	Mod	Mod	Mod	Mod	Mod		
				Headache	Mod	Sev	Mod	Mod	Mod	Mod	Mod		
				Vomiting	Sev	N	N	N	N	N	N	26OCT2020	1
				New or worsened muscle pain	N	Sev	Mod	N	N	Sev	Mod		
	C4591001 1229 12291109	1	05OCT2020	Chills	N	N	N	N	N		Sev	11OCT2020	1
		2	26OCT2020	Fatigue	N	N		N	N	Sev	N	31OCT2020	1
	C4591001 1229 12291113†	2	27OCT2020	Oral temperature (°C)	40	40	40	36.4	36.1	36.4	36.6	29OCT2020	3
	C4591001 1229 12291122	1	06OCT2020	Oral temperature (°C)	39.6	39.9	39.5	39.6	39.4	39.6	39.6	12OCT2020	7
		2	27OCT2020	Oral temperature (°C)	32.6	32.8	39.2	32.5	32.8	32.9	32.7	29OCT2020	1
				Headache	Sev	Mild	N	Mild	N	N	N	30OCT2020	4
	C4591001 1230 12301001	1	23SEP2020	Headache	Sev	Sev	Mild		Mild	N	N	27SEP2020	5
	C4591001 1230 12301018	1	24SEP2020	New or worsened muscle pain	Mod	Sev	N	N	N	N	N	25SEP2020	2

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16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
				New or worsened joint pain	N	Sev	N	N	N	N	N	25SEP2020	1
	C4591001 1230 12301058	2	19OCT2020	Headache	N	Sev	N	N	N	N	N	20OCT2020	1
	C4591001 1230 12301074	1	30SEP2020	Headache	N	N	N	N	Sev	Mod	N	05OCT2020	2
	C4591001 1230 12301084	2	21OCT2020	Oral temperature (°C)	35.3	39.4	37.2	35.9	36.3	35.6	36.4	22OCT2020	1
				Fatigue	N	Sev	Sev	N	N	N	N	23OCT2020	2
	C4591001 1230 12301094	1	01OCT2020	Headache	N	Sev	Sev	N	N	N	N	03OCT2020	2
	C4591001 1230 12301102	2	23OCT2020	Headache	N	Mod	N	Mod	N	Sev	N	28OCT2020	5
	C4591001 1230 12301117	1	03OCT2020	Headache	N	Sev	N	N	N	N	N	04OCT2020	1
	C4591001 1230 12301124	2	27OCT2020	Headache	N	N	N	Sev	N	N	N	30OCT2020	1
	C4591001 1230 12301129	1	05OCT2020	Headache	Mild	Mild	Mild	Sev	Mild	Mild	Mild	12OCT2020	8
	C4591001 1231 12311002	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1231 12311012	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1231 12311018	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1231 12311034	2	02SEP2020	Oral temperature (°C)	36.5	39.9	36.8	36.4	37	36.8	36.3	03SEP2020	1
	C4591001 1231 12311055	2	01SEP2020	Oral temperature (°C)	36.7	39	37.2	36.7		36.5	36.6	02SEP2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
				Fatigue	N	Sev	N	N		Mod	N	06SEP2020	5
				Chills	N	Sev	N	N		N	N	02SEP2020	1
	C4591001 1231 12311082	1	12AUG2020	Fatigue	N	Sev	Mild	Mild	Mild	Mild	Mild	19AUG2020	7
				Chills	N	Sev	N	N	N	N	N	13AUG2020	1
		2	01SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1231 12311092	2	02SEP2020	Headache	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1231 12311099	2	01SEP2020	Fatigue	Mod	Mod	Sev	Mod	Mod	Mod	Mod	12SEP2020	12
	C4591001 1231 12311124	1	13AUG2020	Headache	Mild	Sev	N	N	N	N	N	14AUG2020	2
		2	01SEP2020	Fatigue	Mild	Sev	Mod	Mild	N	N	N	04SEP2020	4
	C4591001 1231 12311125	1	13AUG2020	Headache	Mod	Sev	N	N	N	N	N	14AUG2020	2
				Chills	N	Sev	Mild	Mild	N	N	N	16AUG2020	3
	C4591001 1231 12311144	2	02SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1231 12311164	2	02SEP2020	Fatigue	N	Sev	Mild	Mild	N	Mild	Mild	09SEP2020	7
				Chills	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1231 12311169	2	03SEP2020	Headache	N	Sev	N	N	N		N	04SEP2020	1
	C4591001 1231 12311172	2	04SEP2020	Fatigue	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1231 12311179	1	14AUG2020	Headache	N	Sev	Mild	Mild	Mild	Mild	Mild	21AUG2020	7

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16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1231 12311185	1	14AUG2020	Fatigue	N	Mod	Sev	Mod	Mod	Mod	Mod	21AUG2020	7
				Chills	N	Sev	Mod	Mod	Mod	Mod	Mod	21AUG2020	7
		2	02SEP2020	Headache	Mod	Sev	N	N	N	N	N	03SEP2020	2
	C4591001 1231 12311190	2	03SEP2020	Oral temperature (°C)	36.8	39	37	36.5	36.7	36.7	36.5	04SEP2020	1
	C4591001 1231 12311193	2	04SEP2020	Chills	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1231 12311208	2	04SEP2020	Headache	Mild	Sev	Mild	Mild	Mild	N	N	08SEP2020	5
	C4591001 1231 12311211	2	21SEP2020	New or worsened muscle pain	Mod	Sev	N	Sev	Mod	N	N	25SEP2020	5
				New or worsened joint pain	Mod	Sev	Mod	Mod	Mod	N	N	25SEP2020	5
	C4591001 1231 12311221	2	04SEP2020	Headache	N	Sev	Mild	N	N	Mild	N	09SEP2020	5
	C4591001 1231 12311243	2	04SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1231 12311246	2	02SEP2020	Oral temperature (°C)	37	39	37.4	36.6	36.7	36.6	37.1	03SEP2020	1
				Fatigue	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1231 12311252	2	04SEP2020	Headache	N	Sev	Mild	Mild	N	N	N	07SEP2020	3
	C4591001 1231 12311266	2	02SEP2020	Oral temperature (°C)	37.4	39.1	37.9	36.2	36.4	36.3	36.2	03SEP2020	1
	C4591001 1231 12311272	2	02SEP2020	Headache	N	Sev	Mod	N	Mild	Mod	N	07SEP2020	5
	C4591001 1231 12311281	2	04SEP2020	New or worsened muscle pain	Mild	Sev	N	N	N	N	N	05SEP2020	2

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1231 12311289	1	15AUG2020	Headache	N	Sev	N	N	N	N	N	16AUG2020	1
	C4591001 1231 12311290	1	15AUG2020	Headache	N	Sev	N	N	N	N	N	16AUG2020	1
		2	03SEP2020	Fatigue	N	Sev	N	N	N	N	N	04SEP2020	1
				Headache	N	Sev	N	Mod	Mod	N	N	07SEP2020	4
				Chills	N	Sev	N	N	N	N	N	04SEP2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1231 12311294	1	15AUG2020	New or worsened joint pain	N	N	N	N	Sev	Mild	N	20AUG2020	2
		2	07SEP2020	Fatigue	N	N	N	N	N		Sev	14SEP2020	2
				New or worsened muscle pain	N	N	Sev	N	N		N	09SEP2020	1
	C4591001 1231 12311303	2	04SEP2020	Headache	N	Sev	N	N	N	N	N	05SEP2020	1
				Chills	Mod	Sev	N	N	N	N	N	05SEP2020	2
	C4591001 1231 12311304	2	04SEP2020	Fatigue		Sev	Mild	Mild	Mild	Mild	N	09SEP2020	5
				Chills		Sev	N	N	N	N	N	05SEP2020	1
				New or worsened muscle pain		Sev	Mild	Mild	Mild	Mild	N	09SEP2020	5
	C4591001 1231 12311306	1	15AUG2020	Headache	N	Mod	N	Sev	N	N	N	18AUG2020	3
	C4591001 1231 12311312	2	03SEP2020	Headache	Mild	Sev	N	N	N	N	N	04SEP2020	2
				Chills	Mod	Sev	N	N	N	N	N	04SEP2020	2

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1231 12311317	2	07SEP2020	Headache	Sev	N	N	N	N	N	N	07SEP2020	1
	C4591001 1231 12311327	2	03SEP2020	Fatigue	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1231 12311331	2	03SEP2020	Headache	Mod	Sev	Mild	N	N	N	N	05SEP2020	3
	C4591001 1231 12311361	2	04SEP2020	Oral temperature (°C)	36.4	39	36.2	36.2	36.1	36.2	36.1	05SEP2020	1
				Fatigue	Mild	Sev	Mild	Mild	N	N	N	07SEP2020	4
				Chills	Mild	Sev	Mild	N	N	N	N	06SEP2020	3
				New or worsened joint pain	N	Sev	Mild	N	N	N	N	06SEP2020	2
	C4591001 1231 12311365	2	04SEP2020	Headache	Mild	Sev	N	N	N	N	N	05SEP2020	2
				Chills	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1231 12311368	2	04SEP2020	Oral temperature (°C)	36	39.1	39.2	35.8	35.9	36.6	35.9	06SEP2020	2
	C4591001 1231 12311370	2	03SEP2020	Headache	Mod	Sev	Mild	Mild	N	N	N	06SEP2020	4
				New or worsened muscle pain	Mild	Sev	Mod	Mild	Mild	Mild	N	08SEP2020	6
	C4591001 1231 12311375	2	03SEP2020	New or worsened muscle pain	N	Mild	N	Sev	Mild	N	N	07SEP2020	4
	C4591001 1231 12311386	1	15AUG2020	Headache	N	Sev	N	N	N	N	N	16AUG2020	1
	C4591001 1231 12311410	1	15AUG2020	Fatigue	Mod	Mild	N	N	Mild	Sev		22AUG2020	8
				Chills	N	N	Mild	N	N	Sev		22AUG2020	6

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
				New or worsened muscle pain	N	N	N	N	N	Sev		22AUG2020	3
		2	06SEP2020	Fatigue	N	N	N	Sev	Mod	N	Mod	12SEP2020	4
				Headache	N	Mod	Sev	N	Mod	N	Mod	12SEP2020	6
	C4591001 1231 12311425	2	04SEP2020	Fatigue	Mild	Sev		N		N		05SEP2020	2
				New or worsened muscle pain	N	Sev		N		N		05SEP2020	1
	C4591001 1231 12311432	1	15AUG2020	Headache	N	Sev	Mild	Mild	Mild	N	N	19AUG2020	4
	C4591001 1231 12311454	2	03SEP2020	Fatigue	Mild	Sev	N	N	N	N	N	04SEP2020	2
	C4591001 1231 12311463	1	15AUG2020	Fatigue	Mild	Mod	Mild	N	N	Sev	Mild	23AUG2020	9
	C4591001 1231 12311468	2	03SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1231 12311486	2	07SEP2020	Fatigue	N	Sev	N	N	N	N	N	08SEP2020	1
				New or worsened muscle pain	N	Sev	Mild	Mild	Mod	Mild	Mod	14SEP2020	7
	C4591001 1231 12311507	2	07SEP2020	Fatigue	Mild	Sev	N	N	N	N	N	08SEP2020	2
	C4591001 1231 12311509	2	08SEP2020	Fatigue	N	Sev	N	N	N	N	N	09SEP2020	1
				Headache	Mild	Sev	N	N	N	N	N	09SEP2020	2
	C4591001 1232 12321010	1	13AUG2020	Fatigue							Sev	02SEP2020	15
		2	02SEP2020	Fatigue		Sev	Mild	Mild	Mild	N	Mild	08SEP2020	6

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
				Chills		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1241 12411005	2	26AUG2020	Oral temperature (°C)		39	38.1	37.3	37.2			28AUG2020	2
	C4591001 1241 12411097	1	13AUG2020	Fatigue	N	N	N	N	Mild	Sev	Mod	20AUG2020	4
				Headache	N	N	N	N	Mod	Sev	Sev	20AUG2020	4
	C4591001 1241 12411158	2	08SEP2020	Chills	N	Sev	Sev	N	N	N	N	10SEP2020	2
	C4591001 1241 12411207	2	09SEP2020	Headache	N	Sev	Mod	N	N	N	N	11SEP2020	2
				New or worsened joint pain	N	Sev	N	N	N	N	N	10SEP2020	1
	C4591001 1241 12411262	2	14SEP2020	New or worsened joint pain	N	Mild	Mild	N	Sev	Mild		26SEP2020	12
	C4591001 1246 12461002	2	15OCT2020	Fatigue	N	Sev	N	N	N	N	N	16OCT2020	1
				Headache	N	Sev	N	N	N	N	N	16OCT2020	1
				Chills	N	Sev	N	N	N	N	N	16OCT2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	16OCT2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	16OCT2020	1
	C4591001 1246 12461025	1	28SEP2020	Fatigue	N	Sev	Mild	Mod	Mild	N	Mod		
				Headache	N	Sev	Mod	Mod	Mild	N	Mod		
				Chills	N	Sev	N	N	N	N	N	29SEP2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	29SEP2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
				New or worsened joint pain	N	Sev	N	N	N	N	N	29SEP2020	1
	C4591001 1246 12461038	2	20OCT2020	Diarrhea	N	Sev	Mild			N	N	22OCT2020	2
	C4591001 1246 12461050	2	22OCT2020	Fatigue	Mod	N	Sev	N	N	Mod			
	C4591001 1246 12461052	2	22OCT2020	Headache	N	Sev	Mod	N	N	N		24OCT2020	2
	C4591001 1246 12461055†	1	02OCT2020	Oral temperature (°C)	39.8	36.3	36	36	36.2	37.2	37	02OCT2020	1
	C4591001 1246 12461068	2	23OCT2020	Oral temperature (°C)	36.6	39.2	36.6	36.3	36.2	36.2	36.2	24OCT2020	1
	C4591001 1246 12461090	1	06OCT2020	Fatigue	Mild	Mod	Sev	N	N	N	N	08OCT2020	3
	C4591001 1247 12471010	1	23SEP2020	Headache	Mild	Mild	Mod	N	Mod	Mild	Sev	29SEP2020	7
	C4591001 1247 12471016	2	14OCT2020	Fatigue	N	Sev		N	N			15OCT2020	1
	C4591001 1247 12471033	2	15OCT2020	New or worsened muscle pain	N			Sev	Sev	N	N	19OCT2020	2
	C4591001 1247 12471054	1	29SEP2020	Fatigue	Mod	Mod	Sev	Mod	Mod	Mod	N	04OCT2020	6
	C4591001 1247 12471099	2	20OCT2020	Fatigue	Mild	Sev	N	N	Mild	N	N	24OCT2020	5
	C4591001 1247 12471100	1	29SEP2020	Oral temperature (°C)	40.6	32.2	32.2	33.3			32.2	29SEP2020	1
	C4591001 1247 12471120	2	21OCT2020	Chills	N	Sev	N	N	N	N	N	22OCT2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c		
					1	2	3	4	5	6	7				
>55	C4591001 1247 12471121	1	30SEP2020	Oral temperature (°C)	39.2	39.8	39.1	39.2	39	38.8	38.9	06OCT2020	7		
				Fatigue	Mod	Mod	Mod	Sev	Mod	Mod	Mod			06OCT2020	7
				Headache	Mod	Sev	Mod	Mod	Mod	Mild	Mod			06OCT2020	7
	C4591001 1247 12471145	2	21OCT2020	Oral temperature (°C)	38.9	40	39.6	39.3	38.2	38.9	38.8	26OCT2020	4		
					Fatigue	Mod	Mod	Mod	Mod	Mod	Mod			Sev	
	C4591001 1247 12471172	2	22OCT2020	Headache		Mild	N		Sev	N	N	26OCT2020	4		
					Fatigue	Mild	Sev	Mild	N	Mild	N			N	30OCT2020
	C4591001 1265 12651006	2	26OCT2020	Fatigue		N	Sev	N		Mild	Mild	N	27OCT2020	1	
					Chills	N	Sev	N	N	N	N	N			19SEP2020
	C4591001 1001 10011084	2	14SEP2020	New or worsened muscle pain		N	Sev	N	N	N	N	N	19AUG2020	1	
					Fatigue	N	Sev	N	N	N	N	N			20AUG2020
	C4591001 1001 10011093	2	19AUG2020	Fatigue		N	Sev	N	N	N	N	N	03SEP2020	9	
					Diarrhea	N	Sev	Mild	Mod	N	Mild	Mild			
	C4591001 1005 10051060	2	25AUG2020	Fatigue		N	Sev	N	N	N	N	N	03SEP2020	1	
Chills					N	N	Sev	N	N	N	N	03SEP2020			1
C4591001 1005 10051063	2	01SEP2020	Chills		N	N	Sev	N	N	N	N	03SEP2020	1		
				Fatigue	N	Sev	N	N	N	N	N				
C4591001 1006 10061035	1	14AUG2020	Headache		N	Sev	N	Mild	N	N	N	17AUG2020	3		
				Fatigue	N	Sev	N	Mild	N	N	N				
C4591001 1007 10071114	1	03AUG2020	Fatigue		Mod	Mild	Sev	Sev	Mod	Mod	Mod	22AUG2020	20		
				Chills	N	N	Sev	N	Mild	N	N			07AUG2020	3

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1007 10071120	2	26AUG2020	Fatigue	Mod	Sev	Mod	Mild	N	N	N	29AUG2020	4
	C4591001 1007 10071127	1	05AUG2020	Headache	N	Mild	N	N	N	N	Sev	12AUG2020	7
	C4591001 1009 10091019	2	31AUG2020	Fatigue	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1011 10111014	2	03SEP2020	Fatigue	N	Sev	N	N	N			04SEP2020	1
	C4591001 1011 10111037	2	02SEP2020	Fatigue	N	Sev	Mild	N	N	N	N	04SEP2020	2
	C4591001 1013 10131184	2	03SEP2020	Fatigue	Mod	Sev	Mild	N	N	N	N	05SEP2020	3
	C4591001 1015 10151019	2	02SEP2020	New or worsened muscle pain		Mod	Sev	N	N	N		04SEP2020	2
	C4591001 1016 10161035	2	24AUG2020	Headache	N		Sev	N	Mild	Mild	N	29AUG2020	4
	C4591001 1021 10211004	2	02SEP2020	Fatigue		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1021 10211020	1	12AUG2020	New or worsened muscle pain	N	N	N	Mod	Mod	Sev	N	17AUG2020	3
				New or worsened joint pain	N	N	N	N	N	Sev	N	17AUG2020	1
	C4591001 1022 10221006	2	04SEP2020	Chills		Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1046 10461038	2	05SEP2020	Fatigue	N	Mod	Mod	Mild	Sev	Mod	Mild	11SEP2020	6
	C4591001 1055 10551017	1	10AUG2020	Fatigue	Mild	Sev	Mild		N	N	N	12AUG2020	3

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1073 10731052	2	31AUG2020	Vomiting	N	N	N	N	N	N	Sev	06SEP2020	1
	C4591001 1073 10731072	2	03SEP2020	Chills	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1073 10731078	1	12AUG2020	Diarrhea	N	Sev	Mild	N	N	N	N	14AUG2020	2
		2	03SEP2020	Fatigue	Mod	Sev	Mod	N	N	N	N	05SEP2020	3
	C4591001 1079 10791065	2	26AUG2020	Fatigue		Sev	N	N		N	N	27AUG2020	1
				New or worsened muscle pain		Sev	N	N		N	N	27AUG2020	1
	C4591001 1079 10791084	2	26AUG2020	Fatigue		Sev					N	27AUG2020	1
				Chills		Sev					N	27AUG2020	1
	C4591001 1079 10791111	2	04SEP2020	Headache		N	Sev	Mod	Mod	Mod	Mod	10SEP2020	5
	C4591001 1080 10801006	1	10AUG2020	New or worsened muscle pain	N	N	N	N	Sev	Mod	Mod	31AUG2020	18
	C4591001 1080 10801008	2	31AUG2020	Headache	Mild	Sev	Mod	Mild	N	N	N	03SEP2020	3
	C4591001 1084 10841022	2	24AUG2020	Chills	N	Sev	N	N	N	N	N	25AUG2020	1
	C4591001 1084 10841080	2	28AUG2020	Fatigue	N	Sev	N	N	N	N	N	29AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	29AUG2020	1
	C4591001 1084 10841167	2	04SEP2020	Fatigue	N	Sev	N	N	N	N	N	05SEP2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1084 10841183	2	04SEP2020	New or worsened muscle pain	N	Sev	Mod	Mod	N	N	N	07SEP2020	3
	C4591001 1085 10851074	2	27AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	29AUG2020	2
	C4591001 1087 10871001	2	25AUG2020	New or worsened joint pain	N	Mod	N	Sev	N	N	N	28AUG2020	3
	C4591001 1087 10871024	1	07AUG2020	New or worsened joint pain	N	N	N	N	N	N	Sev	13AUG2020	1
	C4591001 1087 10871039	2	31AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	02SEP2020	2
	C4591001 1087 10871044	2	31AUG2020	Oral temperature (°C)	36.4	39.4	37.4	36.8		36.7	37.1	01SEP2020	1
	C4591001 1088 10881032	1	14AUG2020	New or worsened muscle pain	N	N	N	N	Sev	N	N	18AUG2020	1
	C4591001 1089 10891046	2	27AUG2020	Fatigue	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1090 10901117	2	31AUG2020	Fatigue	Mod	Sev	Mild	Mild	Mild	Mild	N	05SEP2020	6
	C4591001 1090 10901124	2	31AUG2020	Chills	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1090 10901127	2	31AUG2020	Fatigue	Mod	Sev	Mod	Mild	Mild	Mild	Mild		
	C4591001 1090 10901171	1	13AUG2020	Diarrhea		Mild	Sev	Sev	Sev		N	17AUG2020	4
	C4591001 1091 10911059	2	27AUG2020	New or worsened muscle pain	N	N	N	Sev	N	N		30AUG2020	1
	C4591001 1096 10961002	2	04SEP2020	Diarrhea		N	N	Sev	Mild		N	08SEP2020	2

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1107 11071043	1	05AUG2020	Fatigue	N	N	N	N	N	Sev	Mild	11AUG2020	2
				New or worsened joint pain	N	N	N	N	N	Sev	N	10AUG2020	1
	C4591001 1107 11071044	2	26AUG2020	Oral temperature (°C)	37.3	39.9	37.3	37.2	37.2	37.2	37.1	27AUG2020	1
				Fatigue	N	Sev	Mild	Mod	Mod	N	N	30AUG2020	4
				Chills	N	Sev	N	N	Mild	N	N	30AUG2020	4
	C4591001 1107 11071048	2	26AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	28AUG2020	2
	C4591001 1107 11071050	2	26AUG2020	Headache	N	Sev	Mod	Mild	N	N	N	29AUG2020	3
	C4591001 1109 11091008	2	18AUG2020	Chills	N	Sev	Mild	N	N	N	N	20AUG2020	2
	C4591001 1109 11091038	2	18AUG2020	Headache	N	Sev	Sev	Mod	Mild	N	N	22AUG2020	4
	C4591001 1109 11091093	2	24AUG2020	Fatigue	N	Sev	Mild		N	N		26AUG2020	2
				Chills	N	Sev	N		N	N		25AUG2020	1
	C4591001 1109 11091166	2	24AUG2020	Diarrhea	Mild		N	Sev	N	N	N	27AUG2020	4
	C4591001 1109 11091198	2	31AUG2020	Oral temperature (°C)	38.9	37.3	37.2	37.2	37.1	37.4	37.2	31AUG2020	1
	C4591001 1110 11101056	2	28AUG2020	Fatigue	N	Sev	N	N	N		N	29AUG2020	1
	C4591001 1111 11111041	2	27AUG2020	New or worsened joint pain	N	N	N	N	Sev	N	N	31AUG2020	1
	C4591001 1111 11111073	2	31AUG2020	Fatigue	N	Sev	N	N	N	N	N	01SEP2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1111 11111110	2	04SEP2020	Headache	N	Sev	N	N	N	N	N	05SEP2020	1
	C4591001 1112 11121129	2	08SEP2020	Fatigue	N	Sev	Mod	Mild	Mild	Mild	Mild	15SEP2020	7
	C4591001 1112 11121145	2	08SEP2020	Fatigue	N	Sev	Mod	Mild	N	N	N	11SEP2020	3
	C4591001 1118 11181020	2	04SEP2020	Chills	N	Sev	N	N	N	N	N	09SEP2020	1
	C4591001 1118 11181020	2	04SEP2020	New or worsened joint pain	N	Sev	Mod		N		N	06SEP2020	2
	C4591001 1120 11201018	1	31JUL2020	Fatigue	N	N	N	N	Sev	N	N	04AUG2020	1
	C4591001 1120 11201020	2	26AUG2020	Fatigue	N	Sev	N	N	N	N	N	27AUG2020	1
	C4591001 1120 11201059	2	26AUG2020	New or worsened muscle pain	N	N	N	N	Sev	N	N	30AUG2020	1
	C4591001 1120 11201073	1	05AUG2020	Oral temperature (°C)	37.4	38	38.5	37.9	37.9	39.1	38.1	13AUG2020	8
	C4591001 1120 11201127	1	11AUG2020	Diarrhea	N	Mod	Sev						
	C4591001 1120 11201160	2	02SEP2020	New or worsened muscle pain		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1120 11201214	2	08SEP2020	Headache	Mod	Mild	Mod	Mod	Sev	N	N	12SEP2020	5
	C4591001 1120 11201276	2	01OCT2020	New or worsened muscle pain		Sev	N	N	N	N		02OCT2020	1
	C4591001 1123 11231012	2	19AUG2020	New or worsened muscle pain		Sev	N	N	N	N	N	20AUG2020	1
	C4591001 1124 11241031	2	03SEP2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	04SEP2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1124 11241033	2	01SEP2020	Fatigue		Sev	Mod	N	N	Mild	Mild	10SEP2020	9
				Chills		Sev	N	N	N	N	N	02SEP2020	1
				New or worsened muscle pain		Sev	N	N	N	N	N	02SEP2020	1
				New or worsened joint pain		Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1125 11251001	2	01SEP2020	Diarrhea	N	N	N	Mod	Sev	N	N	05SEP2020	2
	C4591001 1129 11291038	2	24AUG2020	Oral temperature (°C)	36.7	38.9	36.9	36.4	36.4	36.3	36.4	25AUG2020	1
	C4591001 1129 11291099	2	31AUG2020	Fatigue	N	Mod	Sev	N	N	N	N	02SEP2020	2
	C4591001 1134 11341016	2	31AUG2020	Fatigue	Mild	Sev	Mild	Mild	Mild	Mod	Mild	08SEP2020	9
	C4591001 1135 11351028	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1135 11351046	2	27AUG2020	Fatigue	Mild	Sev	N	Mild	N	N	N	30AUG2020	4
	C4591001 1135 11351074	2	28AUG2020	Fatigue		Sev	N	N	N		N	29AUG2020	1
				Headache		Sev	N	N	N		N	29AUG2020	1
				New or worsened muscle pain		Sev	N	N	N		N	29AUG2020	1
	C4591001 1135 11351079	2	27AUG2020	Fatigue	N	Sev	N	N	N	N	N	28AUG2020	1
				Chills	N	Sev	N	N	N	N	N	28AUG2020	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	28AUG2020	1

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16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
				New or worsened joint pain	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1135 11351087	1	08AUG2020	Headache	Sev	N	N	N	N	N		08AUG2020	1
	C4591001 1135 11351116	2	01SEP2020	Chills	N	Sev	N	N	N	N		02SEP2020	1
	C4591001 1139 11391057	1	06AUG2020	Fatigue	Mild	Sev	Mild	N	N	N	N	08AUG2020	3
	C4591001 1139 11391088	2	02SEP2020	Fatigue	Mild	Sev	N	N	N		N	03SEP2020	2
	C4591001 1141 11411028	2	26AUG2020	New or worsened muscle pain	N	Mod	Sev	Mod	Mod	N	N	30AUG2020	4
	C4591001 1142 11421012	2	18AUG2020	Fatigue	N	Sev	N	N	N	N	N	19AUG2020	1
	C4591001 1145 11451009	2	02SEP2020	Headache	N	Sev	Mod	N	N	N	N	20AUG2020	2
Fatigue				Mod	Sev	Mild	N	N	N	N	04SEP2020	3	
				New or worsened muscle pain	Mild	Sev	N	N	N	N	N	03SEP2020	2
	C4591001 1147 11471009	2	24AUG2020	Fatigue	N	Mild		Mod	Sev	Mod	Mild		
	C4591001 1147 11471020	2	25AUG2020	Fatigue	N	Sev	N	N	N	N	N	26AUG2020	1
	C4591001 1147 11471082	2	01SEP2020	Diarrhea		Mild	Mod	Mild	Mod	Sev	Mod	27SEP2020	26
	C4591001 1147 11471084	2	31AUG2020	Fatigue	N	Sev	N	N	N	N	Mod	07SEP2020	7
	C4591001 1147 11471116	2	01SEP2020	Oral temperature (°C)	36.9	38.9	37.7	37.1	37.6	37.2	37	02SEP2020	1

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
				Chills	N	Sev	Mild	N	N	N	N	03SEP2020	2
	C4591001 1147 11471124	2	04SEP2020	Fatigue	N	Mod	Mod	Mod	Sev	Mod	N	09SEP2020	5
	C4591001 1163 11631131	2	08SEP2020	New or worsened joint pain		Mild	Sev	N	N	N	N	10SEP2020	2
	C4591001 1224 12241003	1	12AUG2020	Diarrhea	N	N	N	Sev	N	N	N	15AUG2020	1
	C4591001 1226 12261033	2	25AUG2020	Fatigue		Sev	N	N	N	N		26AUG2020	1
				Chills		Sev	N	N	N	N		26AUG2020	1
	C4591001 1226 12261099	2	01SEP2020	Oral temperature (°C)	36.3	39.1	36.8		36.8	36.6	36.7	02SEP2020	1
				Fatigue	N	Sev	N		N	N	N	02SEP2020	1
				Headache	N	Sev	Mild		N	N	N	03SEP2020	2
	C4591001 1229 12291023	1	25SEP2020	Oral temperature (°C)	33.2	36.2	33.1	39.6	35.8			28SEP2020	1
	C4591001 1229 12291056	1	30SEP2020	Oral temperature (°C)	32.8	36.1	36.2	40.7	35.9	35.4	36.2	03OCT2020	1
	C4591001 1229 12291067	2	21OCT2020	Fatigue						Sev	N	26OCT2020	1
				Diarrhea						Sev	N	26OCT2020	1
	C4591001 1229 12291084	2	23OCT2020	Fatigue	Sev								
				New or worsened muscle pain	Sev								
	C4591001 1229 12291123	1	06OCT2020	Oral temperature (°C)	38.2	39.3	37.2	36.8	37.5		36.9	07OCT2020	2

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
	C4591001 1230 12301096	1	01OCT2020	New or worsened muscle pain	N	N	N	N	N	Sev	N	06OCT2020	1
	C4591001 1231 12311007	2	26AUG2020	Fatigue	N	Sev	N	N	N	N	N	27AUG2020	1
				Chills	N	Sev	N	N	N	N	N	27AUG2020	1
	C4591001 1231 12311038	1	11AUG2020	Headache	N	Sev	N	Mild	Mild	N	N	15AUG2020	4
	C4591001 1231 12311146	2	03SEP2020	Fatigue	N	Sev	N	N	N	N	N	04SEP2020	1
				Chills	N	Sev	N	N	N	N	N	04SEP2020	1
	C4591001 1231 12311150	2	01SEP2020	Fatigue	N	Sev	Mod	N	N	N	N	03SEP2020	2
				Headache	N	Sev	Mod	Mild	N	N	N	04SEP2020	3
				New or worsened joint pain	N	Sev	Mod	N	N	N	N	03SEP2020	2
	C4591001 1231 12311292	2	03SEP2020	Fatigue	N	Mod	Mild	Mod	Mild	N	Sev	12SEP2020	9
				New or worsened joint pain	N	N	N	N	N	N	Sev	12SEP2020	4
	C4591001 1231 12311329	2	04SEP2020	Headache	N	Mod	N	Sev	Sev	Sev	Mod		
	C4591001 1231 12311390	1	15AUG2020	Headache	Mild	Sev	Mild	N	N	Mild	Mild	22AUG2020	8

Abbreviations: Dur = duration; Mod = moderate; N = none; Sev = severe.

Note: † = HIV-positive subject.

a. Relative Day (Rel Day) = date of event - date of last vaccination + 1.

b. Stop date is the date the event was last reported.

c. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. If the event continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the event is ongoing at the time of the subsequent vaccination, the end date/day for the event is the date/day that the next vaccine was

16.2.7.3.4 Listing of Severe and Grade 4 Systemic Events – Reactogenicity Subset for Phase 2/3 Analysis

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		

administered, which was used for the duration calculation.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 18NOV2020 (02:59)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_1004_sevse_p3

16.2.7.3.6 Listing of Severe and Grade 4 Systemic Events – Subjects Enrolled in Multiple Sites

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day ^a							Stop Date ^b	Dur (Days) ^c
					1	2	3	4	5	6	7		
No subject meets the reporting criteria.													
<p>a. Relative Day (Rel Day) = date of event - date of last vaccination + 1.</p> <p>b. Stop date is the date the event was last reported.</p> <p>c. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. If the event continued beyond Day 7, the calculation includes all days from the last electronic diary (e-diary) day until the date of resolution collected on the case report form. If the event is ongoing at the time of the subsequent vaccination, the end date/day for the event is the date/day that the next vaccine was administered, which was used for the duration calculation.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (22:37) (Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_1004_sevse_menrol_p3</p>													

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
BNT162b1/ 18-55/ 10 µg/ C4591001 1001 10011004	GENRL	Malaise/ malaise	1	05MAY2020	2/1	1	No	O: related to her poor sleep due to her husband's snoring	NA	R (05MAY2020)	N/N
BNT162b1/ 18-55/ 10 µg/ C4591001 1001 10011006	GENRL	Injection site pain/ soreness at injection site	1	07MAY2020	2/7	1	Yes		NA	R (13MAY2020)	N/N
	SKIN	Dermatitis/ dermatitis	1	09MAY2020	4/3	1	No	O: cat scratches	NA	R (11MAY2020)	N/N
	SKIN	Hand dermatitis/ dermatitis right hand	1	16MAY2020	11/20	1	No	O: probable contact dermatitis	NA	R (04JUN2020)	N/N
		Papule/ micropapules on skin of wrist	1	16MAY2020	11/20	1	No	O: probable contact dermatitis	NA	R (04JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
	SKIN	Dermatitis/ bilateral arm dermatitis	2	01JUN2020	6/4	1	No	O: contact dermatitis	NA	R (04JUN2020)	N/N
BNT162b1/ 18-55/ 10 µg/ C4591001 1001 10011007	GASTR	Diarrhoea/ diarrhea	1	19MAY2020	14/1	1	No	O: food	NA	R (19MAY2020)	N/N
	RESP	Nasal congestion/ Nasal congestion	1	20MAY2020	15/1	1	No	O: secondary to environmental factor	NA	R (20MAY2020)	N/N
BNT162b1/ 18-55/ 10 µg/ C4591001 1001 10011008	IMMUN	Seasonal allergy/ Worsening Seasonal allergies	2	31MAY2020	5/6	1	No	O: Hx of occasional seasonal allergies in past. New onset of mild symptoms	NA	R (05JUN2020)	N/N
	GASTR	Abdominal pain lower/ LLQ abdominal pain	2	06JUN2020	11/8	1	No	O: musculoskeletal or flatulence	NA	R (13JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
BNT162b1/ 18-55/ 10 µg/ C4591001 1001 10011009	CARD	Tachycardia/ mild tachycardia	1	07MAY2020	2/2	1	Yes		NA	R (08MAY2020)	N/N
BNT162b1/ 18-55/ 10 µg/ C4591001 1002 10021011	RESP	Cough/ Cough	1	08MAY2020	3/3	1	Yes		NA	R (10MAY2020)	N/N
	RESP	Dyspnoea/ Shortness of Breath	2	15JUN2020	21/13	1	No	O: Reactive airway disease	NA	R (27JUN2020)	N/N
		Throat irritation/ Throat Irritation	2	15JUN2020	21/13	1	No	O: Seasonal Allergies	NA	R (27JUN2020)	N/N
BNT162b1/ 18-55/ 20 µg/ C4591001 1001 10011068	GASTR	Nausea/ Nausea	1	30JUN2020	2/1	1	Yes		NA/TC	R (30JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
	NERV	Paraesthesia/ Left lower extremity tingling	1	02JUL2020	4/3	1	No	O: musculoskeletal strain due to back exercises	NA	R (04JUL2020)	N/N
	NERV	Neuropathy peripheral/ Bilateral lower extremity neuropathy	2	20JUL2020	1/18	1	No	O: musculoskeletal strain due to back exercises	NA	R (06AUG2020)	N/N
	EYE	Retinal tear/ retinal eye tear	2	29JUL2020	10/2	2	No	O: discovered during a routine eye exam	NA	R (30JUL2020)	N/N
	NERV	Neuropathy peripheral/ neuropathy in right arm	2	30JUL2020	11/8	1	No	O: musculoskeletal strain due to back exercises	NA	R (06AUG2020)	N/N
BNT162b1/ 18-55/ 20 µg/ C4591001 1001 10011071	NERV	Disturbance in attention/ difficulty concentrating post vaccination	1	01JUL2020	1/2	1	Yes		NA	R (02JUL2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
BNT162b1/ 18-55/ 20 µg/ C4591001 1001 10011076		Paraesthesia/ Tingling LE BIL	1	01JUL2020	1/1	1	Yes		NA	R (01JUL2020)	N/Y
	NERV	Dizziness/ lightheadedness	1	09JUL2020	9/1	1	No	O: phlebotomy procedure	NA	R (09JUL2020)	N/N
	PSYCH	Sleep disorder/ sleep disturbance post vaccination	1	01JUL2020	1/2	1	No	O: injection site pain	NA	R (02JUL2020)	N/N
	GENRL	Injection site pain/ injection site tenderness	1	02JUL2020	2/3	1	Yes		NA	R (04JUL2020)	N/N
	SKIN	Rash/ Upper Extremity Rash	1	05JUL2020	5/11	1	No	O: sun exposure	NA	R (15JUL2020)	N/N
	NERV	Headache/ headache	2	22JUL2020	2/2	1	Yes		NA	R (23JUL2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
	GASTR	Abdominal discomfort/ upset stomach	2	25JUL2020	5/3	1	No	O: food related	NA/TC	R (27JUL2020)	N/N
		Diarrhoea/ Loose stools	2	25JUL2020	5/2	1	Yes		NA/TC	R (26JUL2020)	N/N
BNT162b1/ 18-55/ 20 µg/ C4591001 1002 10021080	INJ&P	Muscle strain/ Muscle Strain middle back	1	04JUL2020	4/11	1	No	O: Muscle strain post exercise	NA	R (14JUL2020)	N/N
	NERV	Paraesthesia/ Tingling in both hands	2	21JUL2020	1/1	1	Yes		NA	R (21JUL2020)	N/N
BNT162b1/ 18-55/ 20 µg/ C4591001 1002 10021082	INJ&P	Muscle strain/ Neck Strain	2	24JUL2020	4/3	1	No	O: Incorrect sleep positioning	NA/TC	R (26JUL2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
BNT162b1/ 18-55/ 30 µg/ C4591001 1001 10011011	GENRL	Injection site pain/ tenderness at left arm injection site	1	11MAY2020	1/3	1	Yes		NA	R (13MAY2020)	N/N
	GENRL	Pyrexia/ fever	1	17MAY2020	7/2	1	Yes		NA	R (18MAY2020)	N/N
BNT162b1/ 18-55/ 30 µg/ C4591001 1001 10011012	NERV	Presyncope/ Vaso-vagal reaction with phlebotomy*		13MAY2020	1/1	2	No	O: related to blood collection	NA	R (13MAY2020)	N/N
	CARD	Tachycardia/ tachycardia	1	14MAY2020	2/6	1	Yes		NA	R (19MAY2020)	N/N
BNT162b1/ 18-55/ 30 µg/ C4591001 1001 10011015	CARD	Tachycardia/ tachycardia	1	12MAY2020	2/7	1	Yes		NA	R (18MAY2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
	GENRL	Fatigue/ Fatigue	1	12MAY2020	2/1	1	Yes		NA	R (12MAY2020)	N/N
		Injection site swelling/ injection site swelling at injection site	1	12MAY2020	2/2	1	Yes		NA	R (13MAY2020)	N/N
	METAB	Decreased appetite/ anorexia	2	01JUN2020	1/15	1	Yes		NA	R (15JUN2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	02JUN2020	2/2	1	Yes		NA	R (03JUN2020)	N/N
	GENRL	Chills/ Chills	2	02JUN2020	2/2	2	Yes		NA	R (03JUN2020)	N/N
		Fatigue/ fatigue	2	02JUN2020	2/2	1	Yes		NA	R (03JUN2020)	N/N
		Pyrexia/ Fever (102.4F)	2	02JUN2020	2/2	3	Yes		NA/TC	R (03JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
	NERV	Headache/ Headache	2	02JUN2020	2/4	2	Yes		NA/TC	R (05JUN2020)	N/N
BNT162b1/ 18-55/ 30 µg/ C4591001 1001 10011017	PSYCH	Insomnia/ insomnia	1	13MAY2020	1/2	2	Yes		NA	R (14MAY2020)	N/N
	MUSC	Arthralgia/ Joint pain	1	14MAY2020	2/2	1	Yes		NA	R (15MAY2020)	N/N
		Myalgia/ muscle soreness	1	14MAY2020	2/2	1	Yes		NA	R (15MAY2020)	N/N
BNT162b1/ 18-55/ 30 µg/ C4591001 1001 10011019	GASTR	Nausea/ nausea	1	14MAY2020	2/1	1	Yes		NA	R (14MAY2020)	N/N
	PSYCH	Sleep disorder/ sleep disturbance	2	04JUN2020	2/1	1	Yes		NA	R (04JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
BNT162b1/ 18-55/ 30 µg/ C4591001 1001 10011024	MUSC	Back pain/ back pain	1	13MAY2020	1/2	2	Yes		NA	R (14MAY2020)	N/N
		Musculoskeletal pain/ shoulder pain	1	13MAY2020	1/2	2	Yes		NA	R (14MAY2020)	N/N
Placebo/ 18-55/ Placebo/ C4591001 1001 10011005	INJ&P	Contusion/ deltoid bruise	2	26MAY2020	1/3	1	Yes		NA	R (28MAY2020)	N/N
Placebo/ 18-55/ Placebo/ C4591001 1001 10011069	SKIN	Rash/ Rash	1	18JUL2020	18/4	1	No	O: sun exposure	NA	R (21JUL2020)	N/N
BNT162b1/ 65-85/ 10 µg/	EYE	Eye paraesthesia/ intermittent	1	11JUN2020	1/2	1	Yes		NA/TC	R (12JUN2020)	N/Y

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
C4591001 1001 10011037	NERV	paraesthesia in both eyes Headache/ intermittent headache	2	01JUL2020	2/C	1	No	O: allergic rhinitis	NA	N	N/N
BNT162b1/ 65-85/ 10 µg/ C4591001 1001 10011039	MUSC	Muscle spasms/ worsening leg cramps	1	14JUN2020	6/2	2	No	O: likely related to gardening	NA	R (15JUN2020)	N/N
	GENRL	Fatigue/ fatigue	2	29JUN2020	1/3	1	Yes		NA	R (01JUL2020)	N/N
	GASTR	Aphthous ulcer/ aphthous ulcer	2	04JUL2020	6/4	1	Yes		NA	R (07JUL2020)	N/N
	MUSC	Back pain/ Low back pain	2	07AUG2020	40/C	2	No	CND	NA	N	N/N
BNT162b1/ 65-85/ 10 µg/	RESP	Oropharyngeal pain/ sore throat	2	01AUG2020	31/C	1	No	O: N/A	NA	N	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
C4591001 1001 10011040											
BNT162b1/ 65-85/ 10 µg/ C4591001 1001 10011045	SKIN	Ecchymosis/ echymosis to left deltoid	2	16JUL2020	15/9	1	No	O: injection procedure	NA	R (24JUL2020)	N/N
BNT162b1/ 65-85/ 10 µg/ C4591001 1002 10021043	INJ&P	Skin laceration/ Laceration Right Thumb	1	10JUN2020	2/13	2	No	O: Metal edge of lounge chair	NA	R (22JUN2020)	N/N
	SURG	Suture insertion/ Right Thumb Suture Insertion	1	10JUN2020	2/13	2	No	O: Deep Laceration	NA	R (22JUN2020)	N/N
BNT162b1/ 65-85/ 10 µg/ C4591001 1002 10021044	SKIN	Hyperhidrosis/ Sweating	1	10JUN2020	2/1	1	Yes		NA	R (10JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
	RESP	Dyspnoea/ Shortness of Breath	1	12JUN2020	4/1	1	No	O: Likely related to exercise - moving boxes- 5 minutes	NA	R (12JUN2020)	N/N
BNT162b1/ 65-85/ 10 µg/ C4591001 1002 10021052	MUSC	Back pain/ Lower back pain	1	27JUN2020	17/3	1	No	O: Muscle Strain from work	NA/TC	R (29JUN2020)	N/N
BNT162b1/ 65-85/ 20 µg/ C4591001 1001 10011043	NERV	Dizziness/ Lightheadedness	2	14JUL2020	7/1	1	No	O: Lightheadedness resulted from extra blood draw. Symptoms resolved soon after.	NA	R (14JUL2020)	N/N
BNT162b1/ 65-85/ 20 µg/ C4591001 1001 10011049	GENRL	Fatigue/ intermittent fatigue	2	13JUL2020	8/C	1	Yes		NA	RG	N/N
BNT162b1/ 65-85/ 20 µg/	BLOOD	Anaemia/ Anemia	1	08JUL2020	22/C	2	No	O: Phlebotomy	NA	RG	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
C4591001 1001 10011052											
BNT162b1/ 65-85/ 20 µg/ C4591001 1001 10011055	PSYCH	Sleep disorder/ sleep disturbance	1	18JUN2020	2/1	1	Yes		NA	R (18JUN2020)	N/N
	METAB	Decreased appetite/ Anorexia	2	09JUL2020	2/4	1	Yes		NA	R (12JUL2020)	N/N
BNT162b1/ 65-85/ 20 µg/ C4591001 1001 10011059	GENRL	Injection site pain/ injection site tenderness	1	18JUN2020	2/3	1	Yes		NA	R (20JUN2020)	N/N
	INJ&P	Fall/ Fall	1	03JUL2020	17/1	1	No	O: Slip on a bottom stair	NA	R (03JUL2020)	N/N
		Fibula fracture/ proximal non-	1	03JUL2020	17/5	2	No	O: accidental trauma from slipping from stairs	NA	R (07JUL2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		displaced fracture of the right fibula									
BNT162b1/ 65-85/ 20 µg/ C4591001 1002 10021060	INFEC	Herpes zoster/ Shingles	1	16JUN2020	2/3	3	No	O: Viral Illness	NA/TC	R (18JUN2020)	N/N
	GASTR	Toothache/ Tooth Pain	2	13JUL2020	7/2	1	No	O: Dental Caries	NA/TC	R (14JUL2020)	N/N
	SURG	Tooth extraction/ Tooth Extraction	2	13JUL2020	7/1	1	No	O: Dental Caries	NA/TC	R (13JUL2020)	N/N
BNT162b1/ 65-85/ 20 µg/ C4591001 1002 10021071	GASTR	Nausea/ Nausea	2	09JUL2020	2/1	2	Yes		NA	R (09JUL2020)	N/N
BNT162b1/ 65-85/ 30 µg/	INJ&P	Skin abrasion/ excoriation palms, BIL	2	13JUL2020	5/25	1	No	O: bike accident	NA	R (06AUG2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
C4591001 1001 10011046		Skin abrasion/ excoriation right elbow	2	13JUL2020	5/25	1	No	O: bike accident	NA	R (06AUG2020)	N/N
	MUSC	Pain in extremity/ right thigh pain	2	13JUL2020	5/25	1	No	O: bike accident	NA	R (06AUG2020)	N/N
	INJ&P	Contusion/ right knee bruise	2	16JUL2020	8/22	1	No	O: bike accident	NA/TCN	R (06AUG2020)	N/N
		Fall/ fall	2	16JUL2020	8/1	1	No	O: Fell off his bike	NA	R (16JUL2020)	N/N
		Road traffic accident/ bike accident	2	16JUL2020	8/1	1	No	O: fell off bike	NA	R (16JUL2020)	N/N
	GENRL	Oedema peripheral/ right thigh edema	2	22JUL2020	14/16	1	No	O: Bike Accident	NA	R (06AUG2020)	N/N
BNT162b1/ 65-85/	GENRL	Injection site bruising/	1	16JUN2020	1/15	1	Yes		NA	R (30JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
30 µg/ C4591001 1001 10011048		injection site bruising									
	SKIN	Dermatitis contact/ contact dermatitis	1	16JUN2020	1/4	1	No	O: bandage use	NA	R (19JUN2020)	N/N
	GASTR	Abdominal discomfort/ Abdominal Discomfort	2	09JUL2020	2/2	1	Yes		NA	R (10JUL2020)	N/N
	METAB	Decreased appetite/ Anorexia	2	09JUL2020	2/3	1	Yes		NA	R (11JUL2020)	N/N
	PSYCH	Irritability/ Irritability	2	09JUL2020	2/3	1	Yes		NA	R (11JUL2020)	N/N
BNT162b1/ 65-85/ 30 µg/ C4591001 1001 10011058	SKIN	Ecchymosis/ ecchymosis left arm*		16JUN2020	-2/4	1	No	O: phlebotomy procedure	NA	R (19JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
BNT162b1/ 65-85/ 30 µg/ C4591001 1001 10011063	MUSC	Myalgia/ Left deltoid local site pain	1	18JUN2020	1/3	1	Yes		NA	R (20JUN2020)	N/N
	GENRL	Fatigue/ Fatigue	2	07JUL2020	1/2	3	Yes		NA/TC	R (08JUL2020)	N/N
		Peripheral swelling/ Swelling on left arm 4x2cm	2	07JUL2020	1/16	1	Yes		NA	R (22JUL2020)	N/N
Placebo/ 65-85/ Placebo/ C4591001 1001 10011042	MUSC	Myalgia/ muscle pain	1	12JUN2020	2/2	1	Yes		NA	R (13JUN2020)	N/N
	SKIN	Dermatitis contact/ contact dermatitis	1	12JUN2020	2/2	1	No	O: bandage use	NA	R (13JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade	Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
Placebo/ 65-85/ Placebo/ C4591001 1001 10011053	MUSC	Musculoskeletal pain/ Right Shoulder Pain	1	01JUL2020	16/C	2	No	O: existing condition onset April 2020	NA	N	N/N
Placebo/ 65-85/ Placebo/ C4591001 1001 10011057	INJ&P	Venomous sting/ Jellyfish sting	2	19JUL2020	12/1	1	No	O: Unrelated	NA	R (19JUL2020)	N/N
Placebo/ 65-85/ Placebo/ C4591001 1002 10021050	RESP	Oropharyngeal pain/ Sore Throat	1	16JUN2020	2/1	1	No	O: Allergies	NA	R (16JUN2020)	N/N
BNT162b2/ 18-55/ 10 µg/ C4591001 1003 10031020	MUSC	Muscle spasms/ worsening leg cramps left calf	2	10JUL2020	9/5	2	No	O: history of leg cramps	NA	R (14JUL2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
BNT162b2/ 18-55/ 10 µg/ C4591001 1007 10071014	MUSC	Myalgia/ LEFT SHOULDER MUSCLE PAIN	1	18JUN2020	8/16	2	No	O: Thought due to sleeping with his arm in an odd position.	NA/TC	R (03JUL2020)	N/N
		Myalgia/ Left Scapula area muscle pain	1	18JUN2020	8/16	2	No	O: The participant likely slept with his arm in an odd position.	NA/TC	R (03JUL2020)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection	1	27JUN2020	17/11	1	No	O: Urinary tract infection	NA/TC	R (07JUL2020)	N/N
	RENAL	Nephrolithiasis/ renal calculi	1	27JUN2020	17/23	2	No	O: Kidney stone, most commonly due to mild dehydration.	NA/TC/TCN	R (19JUL2020)	N/N
BNT162b2/ 18-55/ 10 µg/	GENRL	Injection site pain/ tenderness at injection site	1	08JUN2020	1/1	1	Yes		NA	R (08JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
C4591001 1007 10071019	RESP	Rhinorrhoea/ nasal drainage	2	03JUL2020	5/8	1	No	O: viral infection	NA/TC	R (10JUL2020)	N/N
BNT162b2/ 18-55/ 10 µg/ C4591001 1007 10071021	GENRL	Injection site erythema/ redness at injection site	1	10JUN2020	1/1	1	Yes		NA	R (10JUN2020)	N/Y
BNT162b2/ 18-55/ 20 µg/ C4591001 1003 10031030	INJ&P	Ligament sprain/ Right sprained ankle	2	06AUG2020	30/C	1	No	O: Accident	NA	RG	N/N
BNT162b2/ 18-55/ 20 µg/ C4591001 1007 10071017	GENRL	Injection site pain/ left injection site arm pain	1	15JUN2020	1/3	1	Yes		NA	R (17JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
BNT162b2/ 18-55/ 20 µg/ C4591001 1007 10071026	SKIN	Rash papular/ erythematous papular rash chest, forehead, cheek	2	12JUL2020	7/7	1	Yes		NA/TC	R (18JUL2020)	N/N
BNT162b2/ 18-55/ 20 µg/ C4591001 1007 10071027	PSYCH	Sleep disorder/ Sleep disturbance	1	17JUN2020	1/4	1	Yes		NA	R (20JUN2020)	N/N
BNT162b2/ 18-55/ 20 µg/ C4591001 1007 10071029	NERV	Ageusia/ partial loss of taste	1	17JUN2020	1/1	1	Yes		NA	R (17JUN2020)	N/Y
	NERV	Taste disorder/ change in sensation of taste	2	08JUL2020	1/2	1	Yes		NA	R (09JUL2020)	N/Y
BNT162b2/ 18-55/ 30 µg/	INJ&P	Fall/ fall while exercising	1	24JUN2020	3/1	2	No	O: fall	NA/TCN	R (24JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
C4591001 1003 10031066		Tendon injury/ Achilles tendon injury	1	24JUN2020	3/7	2	No	O: fall	NA/TCN	R (30JUN2020)	N/N
BNT162b2/ 18-55/ 30 µg/ C4591001 1007 10071046	NERV	Migraine/ Migraine Exacerbation	1	28JUN2020	7/2	3	No	O: Subject with a history of migraines; this was an exacerbation.	NA	R (29JUN2020)	N/N
BNT162b2/ 18-55/ 30 µg/ C4591001 1007 10071050	BLOOD	Lymphadenopathy/ Right axillary lymph node enlargement	2	15JUL2020	3/13	1	Yes		NA	R (27JUL2020)	N/N
BNT162b2/ 18-55/ 30 µg/ C4591001 1007 10071063	GENRL	Injection site pain/ soreness at injection site	1	24JUN2020	1/1	1	Yes		NA	R (24JUN2020)	N/Y

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
BNT162b2/ 18-55/ 30 µg/ C4591001 1007 10071066	NERV	Dizziness/ Dizziness	2	16JUL2020	2/1	2	Yes		NA/TCN	R (16JUL2020)	N/N
Placebo/ 18-55/ Placebo/ C4591001 1007 10071020	GENRL	Injection site erythema/ redness at injection site	1	10JUN2020	1/1	1	Yes		NA	R (10JUN2020)	N/N
Placebo/ 18-55/ Placebo/ C4591001 1007 10071025	GASTR	Oral disorder/ oral lesion	1	29JUN2020	13/12	1	No	O: oral HSV outbreak	NA/TC	R (10JUL2020)	N/N
BNT162b2/ 65-85/ 10 µg/ C4591001 1007 10071071	INJ&P	Contusion/ coccyx contusion	1	04JUL2020	6/18	1	No	O: injury	NA	R (21JUL2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		Contusion/ right knee contusion	1	04JUL2020	6/C	1	No	O: injury	NA	RG	N/N
		Fall/ fall from side of bathtub	1	04JUL2020	6/1	1	No	O: lost balance	NA	R (04JUL2020)	N/N
BNT162b2/ 65-85/ 20 µg/ C4591001 1003 10031035	NERV	Presyncope/ near syncope	2	06AUG2020	32/1	1	No	O: blood draw	NA	R (06AUG2020)	N/N
BNT162b2/ 65-85/ 20 µg/ C4591001 1007 10071052	GASTR	Nausea/ nausea	1	18JUN2020	2/2	2	Yes		NA	R (19JUN2020)	N/N
	GASTR	Nausea/ Nausea	1	22JUN2020	6/2	1	Yes		NA	R (23JUN2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
BNT162b2/ 65-85/ 30 µg/ C4591001 1003 10031058	MUSC	Muscle spasms/ Worsening leg cramping	2	10JUL2020	2/5	3	No	O: has history of leg cramping	NA	R (14JUL2020)	N/N
BNT162b2/ 65-85/ 30 µg/ C4591001 1007 10071043	NERV	Sciatica/ exacerbation of sciatica	1	22JUN2020	5/26	1	No	O: Flare of pre-existing condition	NA/TC/TCN	R (17JUL2020)	N/N
BNT162b2/ 65-85/ 30 µg/ C4591001 1007 10071049	VASC	Hypertension/ Hypertension	2	13JUL2020	5/C	2	No	O: new onset medical condition	NA/TC	N	N/N
Placebo/ 65-85/ Placebo/ C4591001 1003 10031083	NERV	Radiculopathy/ worsening radiculitis	1	03JUL2020	3/6	3	No	O: history of radiculopathy	NA	R (08JUL2020)	N/N

16.2.7.4.1 Listing of Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
Placebo/ 65-85/ Placebo/ C4591001 1007 10071075	SURG	Tooth extraction/ Tooth extraction	1	12JUL2020	13/1	2	No	O: Tooth extraction; Pre-planned extraction	NA/TC	R (12JUL2020)	N/N
	SURG	Tooth extraction/ tooth extraction	1	14JUL2020	15/1	2	No	O: dental extraction of fractured tooth for placement of dental implant	NA/TCN	R (14JUL2020)	N/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: * = Prevaccination AE.

Note: MedDRA (v23.0) coding dictionary applied.

a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 29AUG2020 (09:41)

(Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adae 1002 p1

16.2.7.4.1.1 Listing of Adverse Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
BNT162b1/ 18-55/ 100 µg/ C4591001 1001 10011026	CARD	Tachycardia/ tachycardia	1	18MAY2020	1/2	1	Yes		NA	R (19MAY2020)	N/N
BNT162b1/ 18-55/ 100 µg/ C4591001 1001 10011028	PSYCH	Sleep disorder/ Sleep disturbance	1	20MAY2020	1/4	2	Yes		NA	R (23MAY2020)	N/N
	MUSC	Pain in extremity/ Left plantar heel pain	1	16JUL2020	58/13	2	No	O: Plantar fasciitis	NA/TCN	R (28JUL2020)	N/N
BNT162b1/ 18-55/ 100 µg/ C4591001 1001 10011030	PSYCH	Sleep disorder/ Moderate sleep disturbance	1	20MAY2020	1/9	2	Yes		NA	R (28MAY2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	21MAY2020	2/4	1	Yes		NA	R (24MAY2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
	MUSC	Myalgia/ muscle pain	1	21MAY2020	2/2	1	Yes		NA	R (22MAY2020)	N/N
BNT162b1/ 18-55/ 100 µg/ C4591001 1001 10011032	GENRL	Injection site erythema/ Injection site redness	1	24MAY2020	5/2	1	Yes		NA	R (25MAY2020)	N/N
BNT162b1/ 18-55/ 100 µg/ C4591001 1001 10011034	NERV	Presyncope/ Vaso-vagal reaction with finger prick*		15MAY2020	-5/1	2	No	O: vaso-vagal reaction with finger prick	NA	R (15MAY2020)	N/N
	GASTR	Nausea/ nausea	1	20MAY2020	1/6	2	Yes		NA	R (25MAY2020)	N/N
	PSYCH	Sleep disorder/ sleep disturbance	1	20MAY2020	1/3	3	Yes		NA	R (22MAY2020)	N/N
	METAB	Decreased appetite/ loss of appetite	1	21MAY2020	2/24	2	Yes		NA	R (13JUN2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
	NERV	Presyncope/ vasovagal reaction	1	09JUL2020	51/1	2	No	O: phlebotomy	NA	R (09JUL2020)	N/N
BNT162b1/ 18-55/ 100 µg/ C4591001 1002 10021023	INFEC	Hordeolum/ Stye right lower eyelid	1	13AUG2020	88/8	1	No	O: Infected hair follicle	NA/TC	R (20AUG2020)	N/N
BNT162b1/ 18-55/ 100 µg/ C4591001 1002 10021024	GASTR	Nausea/ Nausea	1	18MAY2020	1/3	2	Yes		NA	R (20MAY2020)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection	1	21MAY2020	4/11	1	No	O: Community- acquired infection	NA/TC	R (31MAY2020)	N/N
	INJ&P	Wound/ Shoulder Wound	1	25JUN2020	39/13	1	No	O: Traumatic injury caused by foreign body	NA/TC	R (07JUL2020)	N/N

16.2.7.4.1.1 Listing of Adverse Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
BNT162b1/ 18-55/ 100 µg/ C4591001 1002 10021036	GENRL	Fatigue/ Fatigue	1	16JUN2020	27/13	1	No	O: Thyroid level low.	NA/TC	R (28JUN2020)	N/N
	RESP	Sinus congestion/ Sinus Fullness	1	16JUN2020	27/11	1	No	O: unknown	NA	R (26JUN2020)	N/N
Placebo/ 18-55/ Placebo/ C4591001 1001 10011021	GASTR	Paraesthesia oral/ Tingling sensation of mouth	1	20MAY2020	1/1	1	Yes		NA	R (20MAY2020)	N/N
	RESP	Pharyngeal paraesthesia/ Tingling sensation of throat	1	20MAY2020	1/1	1	Yes		NA	R (20MAY2020)	N/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: * = Pre vaccination AE.

Note: MedDRA (v23.0) coding dictionary applied.

a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.

16.2.7.4.1.1 Listing of Adverse Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate/ Age Group (Years)/ Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day^a/ Dur (Days)^b	Toxicity Vax Grade	Rel^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 18SEP2020 (18:51) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001 IA P1 100/adae 1002 100 p1											

16.2.7.4.2 Listing of Adverse Events – Phase 2

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
18-55/ C4591001 1007 10071083	RESP	Oropharyngeal pain/ sore throat	1	05AUG2020	9/2	1	No	O: Exposure to dry ambient air	NA	R (06AUG2020)	N/N
18-55/ C4591001 1007 10071097	MUSC	Myalgia/ Scapular Muscle Pain	2	21AUG2020	2/C	3	No	O: possible muscle spasm. Unclear exact etiology	NA/TC/TCN	RG	N/N
	BLOOD	Lymphadenopathy/ Bilateral Swollen Cervical Lymph Nodes	2	23AUG2020	4/C	1	No	O: Possible viral syndrome	NA/TC	RG	N/N
18-55/ C4591001 1013 10131003	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	28JUL2020	1/11	1	Yes		NA	R (07AUG2020)	N/N
	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	09AUG2020	13/C	1	Yes		NA	RG	N/N
18-55/ C4591001 1013 10131006	MUSC	Myalgia/ MUSCLE PAIN	1	04AUG2020	8/1	2	Yes		NA	R (04AUG2020)	N/N
18-55/ C4591001 1013 10131014	GENRL	Fatigue/ FATIGUE	1	31JUL2020	3/C	1	Yes		NA	RG	N/N

16.2.7.4.2 Listing of Adverse Events – Phase 2

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
18-55/ C4591001 1013 10131015	GASTR	Diarrhoea/ DIARRHEA	1	29JUL2020	1/8	1	Yes		NA	R (05AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	29JUL2020	1/8	2	Yes		NA	R (05AUG2020)	N/N
18-55/ C4591001 1013 10131021	GASTR	Diarrhoea/ DIARRHEA	1	13AUG2020	15/9	2	No	O: FOOD	NA	R (21AUG2020)	N/N
18-55/ C4591001 1013 10131032	NERV	Headache/ HEADACHE	1	05AUG2020	7/2	1	Yes		NA	R (06AUG2020)	N/N
18-55/ C4591001 1079 10791004	NEOPL	Adenocarcinoma gastric/ INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	1	20AUG2020	23/C	3	No	O: n/a	P/W	N	Y/N
18-55/ C4591001 1079 10791010	RESP	Productive cough/ Wet Cough	1	30JUL2020	1/1	1	No	O: Unknown	NA	R (30JUL2020)	N/N
		Rhinorrhoea/ Runny Nose	1	30JUL2020	1/1	1	No	O: Unknown	NA	R (30JUL2020)	N/N

16.2.7.4.2 Listing of Adverse Events – Phase 2

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
18-55/ C4591001 1083 10831004	SKIN	Hangnail/ Hang Nail	1	31JUL2020	3/C	1	No	O: per PI skin disorder	NA/TC	RG	N/N
18-55/ C4591001 1095 10951005	MUSC	Arthralgia/ polyarthralgias	1	06AUG2020	8/C	1	No	O: etiology indeterminate	NA	N	N/N
18-55/ C4591001 1107 11071003	GASTR	Tongue discomfort/ BURNT SENSATION ON TONGUE	1	11AUG2020	14/C	1	Yes		NA	N	N/N
18-55/ C4591001 1107 11071010	INFEC	Vulvovaginal mycotic infection/ YEAST INFECTION VAGINAL	1	11AUG2020	13/7	1	No	O: UNKNOWN	NA/TC	R (17AUG2020)	N/N
18-55/ C4591001 1109 11091002	GENRL	Injection site pain/ Injection site tenderness	1	29JUL2020	1/1	1	Yes		NA	R (29JUL2020)	N/N
18-55/ C4591001 1109 11091010	GENRL	Injection site pain/ injection site tenderness	1	29JUL2020	1/3	2	Yes		NA/TC	R (31JUL2020)	N/N
18-55/ C4591001	INJ&P	Contusion/ contusion of right hip	1	13AUG2020	15/C	1	No	O: fall	NA	N	N/N

16.2.7.4.2 Listing of Adverse Events – Phase 2

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1109 11091016		Contusion/ contusion to pelvis	1	13AUG2020	15/C	1	No	O: fall	NA	N	N/N
		Fall/ FALL FROM STEP	1	13AUG2020	15/1	1	No	O: FALL	NA	RS (13AUG2020)	N/N
18-55/ C4591001 1109 11091030	GENRL	Injection site erythema/ Injection Site Redness	1	30JUL2020	1/2	1	Yes		NA	R (31JUL2020)	N/N
56-85/ C4591001 1001 10011099	GENRL	Chills/ Chills	1	15AUG2020	17/2	1	No	O: N/A	NA	R (16AUG2020)	N/N
56-85/ C4591001 1001 10011100	SKIN	Dermatitis/ Dermatitis with red patch on left abdomen	1	10AUG2020	12/C	1	No	O: Unspecified	NA/TC	RG	N/N
		Dermatitis/ Dermatitis with red patch on right breast	1	10AUG2020	12/C	1	No	O: Unspecified non-allergy	NA/TC	RG	N/N
		Rash macular/ macular rash on neck	1	10AUG2020	12/16	2	No	O: poison ivy	NA/TC	R (25AUG2020)	N/N

16.2.7.4.2 Listing of Adverse Events – Phase 2

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
	SKIN	Dermatitis/ Dermatitis with red patch from left areola extending laterally	1	13AUG2020	15/C	1	No	O: unspecified non-allergic reaction	NA/TC	RG	N/N
56-85/ C4591001 1003 10031091	INJ&P	Contusion/ Bruising on the upper left arm deltoid region	1	05AUG2020	10/C	1	Yes		NA	RG	N/N
56-85/ C4591001 1003 10031092	INJ&P	Tendon rupture/ Torn Lateral Epicondyle tendon	1	09AUG2020	13/C	2	No	O: Medical History of tendon issues - due to physical stress during activity.	NA/TC	RG	N/N
56-85/ C4591001 1003 10031099	GENRL	Injection site swelling/ Swelling at injection site	1	31JUL2020	4/10	1	Yes		NA	R (09AUG2020)	N/N
56-85/ C4591001 1003 10031105	GASTR	Odynophagia/ occasional odynophagia	1	12AUG2020	15/6	1	No	O: unknown	NA	R (17AUG2020)	N/N
	MUSC	Neck pain/ Left sided neck pain	1	12AUG2020	15/6	1	No	O: unknown	NA	R (17AUG2020)	N/N
56-85/ C4591001	GASTR	Diarrhoea/ Diarrhea	1	05AUG2020	8/2	1	No	O: Unknown - mild case less than 24 hours	NA	R (06AUG2020)	N/N

16.2.7.4.2 Listing of Adverse Events – Phase 2

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1003 10031107											
56-85/ C4591001 1003 10031109	INJ&P	Muscle rupture/ Torn Right Bicep Muscle	1	13AUG2020	15/C	2	No	O: Noticed after playing tennis - on the same arm as vaccination #1 on 30Jul2020	NA	RG	N/N
56-85/ C4591001 1089 10891004	INV	White blood cell count increased/ elevated white count	1	10AUG2020	13/C	2	No	O: unknown	NA/TC	N	N/N
56-85/ C4591001 1139 11391004	GENRL	Injection site erythema/ Erythema Distal to Injection Site	2	20AUG2020	1/1	1	No	O: Pressure from holding arm during injection	NA	R (20AUG2020)	N/N
56-85/ C4591001 1139 11391005	GENRL	Injection site discolouration/ Discoloration at injection site	1	29JUL2020	1/16	1	Yes		NA	R (13AUG2020)	N/N
56-85/ C4591001 1141 11411001	SKIN	Macule/ Skin Macule on left upper arm	1	06AUG2020	8/C	1	Yes		NA	N	N/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.0) coding dictionary applied.

a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not

16.2.7.4.2 Listing of Adverse Events – Phase 2

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Vax Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
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added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:08) Source Data: adae Table Generation: 10SEP2020 (21:41)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adae_i002_p2

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1001 10011083	3^	INFEC	Urinary tract infection/ urinary tract infection	2	14SEP2020	27/7	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C459100 1 1001 10011092	2^	GENRL	Chest discomfort/ intermittent chest discomfort	2	14SEP2020	27/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1001 10011106	3^	MUSC	Back pain/ Lower Back Pain	1	02AUG2020	3/2	2	Yes		NA	R (03AUG2020)	N/N
16-55/ C459100 1 1001 10011113	3^	NERV	Migraine/ worsening migraine	1	07AUG2020	5/9	2	No	O	NA	R (15AUG2020)	N/N
16-55/ C459100 1 1001 10011125	3^	NERV	Dizziness/ dizziness*		04AUG2020	1/1	1	Yes		NA	R (04AUG2020)	N/N
		NERV	Migraine/ migraine headache	1	05AUG2020	2/5	3	Yes		NA	R (09AUG2020)	N/N
		MUSC	Myalgia/ diffuse myalgias	1	06AUG2020	3/2	3	Yes		NA	R (07AUG2020)	N/N
		PSYCH	Disorientation/ disorientation	1	08AUG2020	5/2	1	No	O	NA	R (09AUG2020)	N/N
16-55/ C459100 1 1001 10011130	3^	INJ&P	Arthropod bite/ Insect bites, left ankle	1	07AUG2020	3/3	1	No	O	NA/TC	R (09AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1001 10011132	3^	RESP	Allergic respiratory disease/ Allergy upper respiratory	2	01SEP2020	7/3	1	No	O	NA	R (03SEP2020)	N/N
16-55/ C459100 1 1001 10011138	3^	MUSC	Arthralgia/ exacerbation of history of left shoulder pain	2	15SEP2020	20/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1001 10011143	3^	MUSC	Pain in extremity/ right arm pain	2	11SEP2020	16/3	1	No	O	NA	R (13SEP2020)	N/N
16-55/ C459100 1 1001 10011145	3^	GASTR	Gastroesophageal reflux disease/ exacerbation of gastroesophageal reflux disease	2	03SEP2020	7/2	1	No	O	NA	R (04SEP2020)	N/N
		INV	Body temperature increased/ elevated temperature	2	03SEP2020	7/1	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 1 1001 10011149	3^	GENRL	Malaise/ Malaise	1	14AUG2020	8/5	1	No	O	NA	R (18AUG2020)	N/N
		INJ&P	Muscle strain/ muscle strain	2	23SEP2020	27/3	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C459100 1 1003 10031101	2^	SKIN	Dermatitis contact/ poison ivy	2	09SEP2020	23/15	2	No	O	NA/TC	RS (23SEP2020)	N/N
		VASC	Hypertension/ Hypertension	2	16SEP2020	30/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1003 10031111	2^	MUSC	Tenosynovitis/ Tenosynovitis	2	26SEP2020	38/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1003 10031125	3^	METAB	Obesity/ obesity	2	03SEP2020	14/C	3	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 1 1003 10031147	3^	VASC	Hypertension/ worsening hypertension	2	SEP2020	7/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1003 10031155	3^	GENRL	Fatigue/ Mild Fatigue	1	11AUG2020	6/2	1	No	O	NA	R (12AUG2020)	N/N
16-55/ C459100 1 1003 10031160	3^	INJ&P	Contusion/ traumatic bruise left knee	1	10AUG2020	5/6	2	No	O	NA/TC	R (15AUG2020)	N/N
			Fall/ fall from bicycle	1	10AUG2020	5/6	2	No	O	NA/TC	R (15AUG2020)	N/N
16-55/ C459100 1 1003 10031201	3^	IMMUN	Hypersensitivity/ Allergy Attack	2	20SEP2020	18/1	1	No	O	NA/TC	R (20SEP2020)	N/N
		INFEC	Sinusitis/ Sinus Infection	2	22SEP2020	20/4	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C459100	3^	GASTR	Colitis ulcerative/ ulcerative colitis	2	24OCT2020	51/16	3	No	O	NA	R (08NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1003 10031206 16-55/ C459100	3^	MUSC	Back pain/ BACK PAIN	2	30SEP2020	32/C	2	No	O	NA/TC	N	N/N
1 1005 10051003 16-55/ C459100	3^	METAB	Decreased appetite/ DECREASED APPETITE	2	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N
1 1005 10051024 16-55/ C459100	3^	EAR	Vertigo positional/ INTERMITTENT POSITIONAL VERTIGO	1	13AUG2020	3/5	1	Yes		NA	R (17AUG2020)	N/N
1 1005 10051026 16-55/ C459100	3^	GENRL	Non-cardiac chest pain/ INTERMITTENT NON CARDIAC CHEST PAIN	2	09SEP2020	6/9	2	No	O	NA	R (17SEP2020)	Y/N
1 1005 10051054 16-55/ C459100	3^	GENRL	Fatigue/ FATIGUE	1	19AUG2020	7/2	1	Yes		NA	R (20AUG2020)	N/N
1 1005 10051055 16-55/ C459100	3^	MUSC	Myalgia/ MUSCLE PAIN	1	19AUG2020	7/2	1	Yes		NA	R (20AUG2020)	N/N
1 1005 10051066 16-55/ C459100	3^	GENRL	Chills/ CHILLS	2	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1005 10051075	3^	GENRL	Fatigue/ FATIGUE	2	06SEP2020	3/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1005 10051076	3^	GENRL	Chills/ CHILLS	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
			Malaise/ MALAISE	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ MYALGIA	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
		GENRL	Pyrexia/ FEVER 100.9	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1005 10051077	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
		MUSC	Myalgia/ MYALGIA	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
16-55/ C459100 1 1005 10051081	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/Y
			Injection site warmth/ CALOR AT INJECTION SITE	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1005 10051082	3^	GASTR	Diarrhoea/ DIARRHEA	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
		INFE	Gastroenteritis/ GASTROENTERITIS	1	10SEP2020	23/C	1	Yes		NA	N	N/N
		GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
		NERV	Depressed level of consciousness/ CLOUDING OF CONCIOUSNESS	1	05SEP2020	18/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1005 10051084	3^	EYE	Conjunctival oedema/ RIGHT EYE CONJUNCTIVA SWELLING	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
			Eye irritation/ RIGHT EYE IRRITATION	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
			Ocular hyperaemia/ RIGHT EYE ERYTHEMA	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1005 10051093	3^	NERV	Dizziness/ DIZZINESS	2	21SEP2020	12/4	1	No	O	NA	R (24SEP2020)	N/N
			Dizziness/ LIGHT HEADED	2	21SEP2020	12/4	1	No	O	NA	R (24SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ SORE INJECTION SITE ARM RADIATING TO NECK	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1005 10051100		GENRL	Chills/ CHILLS	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ FEVER	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		MUSC	Myalgia/ MYALGIA	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1005 10051107	3^	GENRL	Malaise/ MALAISE	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C459100 1 1005 10051119	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE*		24AUG2020	1/4	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 1 1005 10051123	3^	MUSC	Myalgia/ Muscle Aches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		INFEC	Urinary tract infection/ URINATRY TRACT INFECTION	2	14OCT2020	31/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1005 10051125	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	25AUG2020	2/5	1	Yes		NA	R (29AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1005 10051129	3^	GENRL	Chills/ CHILLS	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
			Fatigue/ FATIGUE	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	24AUG2020	1/5	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Asthenia/ ASTHENIA	1	26AUG2020	3/1	1	Yes		NA/TC	R (26AUG2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA	1	28AUG2020	4/1	1	Yes		NA	R (28AUG2020)	N/N
		RESP	Oropharyngeal pain/ SORE THROAT	1	28AUG2020	4/1	1	Yes		NA	R (28AUG2020)	N/N
		GASTR	Diarrhoea/ INTERMITTENT DIARRHEA	1	02SEP2020	9/13	1	Yes		NA	R (14SEP2020)	N/N
GENRL	Injection site pain/ INJECTION SITE PAIN	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1005 10051146	3^	MUSC	Pain in extremity/ RIGHT LEG PAIN	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		RESP	Oropharyngeal pain/ SORE THROAT	2	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N
		RESP	Oropharyngeal pain/ SORE THROAT	2	19SEP2020	6/1	1	No	O	NA	R (19SEP2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA	2	20SEP2020	7/1	1	No	O	NA	R (20SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	25AUG2020	1/2	1	Yes		NA/TC	R (26AUG2020)	N/Y
		MUSC	Myalgia/ GENERALIZED MYALGIA	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
		GASTR	Nausea/ NAUSEA	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
		GENRL	Asthenia/ WEAKNESS	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
		MUSC	Pyrexia/ FEVER	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		MUSC	Arthralgia/ GENERALIZED ARTHRALGIA	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	16SEP2020	3/1	2	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11005 10051150	3^	NERV	Nerve compression/ PINCHED NERVE IN NECK	2	15SEP2020	2/C	2	Yes		NA/TC	N	N/N
16-55/ C459100 11005 10051151	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 11005 10051161	3^	GENRL	Chills/ CHILLS	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 11005 10051165	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA	1	14SEP2020	20/2	1	No	O	NA	R (15SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1005 10051168	3^	MUSC	Pyrexia/ FEVER 100.5	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
			Costochondritis/ LEFT CHOSTOCHONDRITIS	1	16SEP2020	21/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1005 10051169	3^	METAB	Decreased appetite/ LACK OF APPETITE	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		MUSC	Musculoskeletal stiffness/ LEFT SHOULDER STIFFNESS	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
			Musculoskeletal stiffness/ STIFFNESS ON LEFT SIDE OF NECK	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		NERV	Dizziness/ LIGHT HEADED	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
			Headache/ HEADACHE	1	27AUG2020	1/2	1	Yes		NA/TC	R (28AUG2020)	N/N
		NERV	Lethargy/ LETHARGY	1	29AUG2020	3/3	2	Yes		NA	R (31AUG2020)	N/N
16-55/ C459100 1 1005 10051171	3^	GASTR	Dyspepsia/ HEARTBURN	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
			Nausea/ NAUSEA	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Migraine/ WORSENING OF MIGRINES	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 11005 10051178	3 [^]	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N	
			IMMUN	Allergy to arthropod sting/ BEE STING REACTION	1	11SEP2020	15/5	1	No	O	NA/TC	R (15SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N	
			Fatigue/ FATIGUE	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	
			Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	
			Pyrexia/ FEVER 100.4	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N	
			MUSC	Arthralgia/ GENERALIZED ARTHRALGIA	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
			Myalgia/ GENERALIZED MYALGIA	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N	
GASTR	Vomiting/ EMESIS	2	01OCT2020	14/1	2	No	O	NA	R (01OCT2020)	N/N			
16-55/ C459100 11005 10051179	3 [^]	EYE	Eye pain/ STINGING IN EYES	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N	
			RESP	Cough/ COUGH	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/Y
			Throat irritation/ TICKLE IN THROAT	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/Y	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1005 10051181	3^	GENRL	Upper-airway cough syndrome/ POST NASAL DRIP	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 1 1005 10051182	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
		GENRL	Fatigue/ EXTREME FATIGUE	1	29AUG2020	2/1	2	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 1 1005 10051183	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	31AUG2020	1/7	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Pain/ BODY ACHES	1	01SEP2020	2/3	1	Yes		NA/TC	R (03SEP2020)	N/N
16-55/ C459100 1 1005 10051187	3^	RESP	Cough/ COUGH	1	01SEP2020	2/3	1	Yes		NA/TC	R (03SEP2020)	N/N
		GENRL	Nasal congestion/ NASAL CONGESTION	1	01SEP2020	2/3	1	Yes		NA/TC	R (03SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	24/6	1	Yes		NA	R (28SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1005 10051188	3^	GENRL	Fatigue/ FATIGUE	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	01SEP2020	1/3	2	Yes		NA	R (03SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	1	01SEP2020	1/8	1	Yes		NA	R (08SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1005 10051192	3^		Injection site pain/ INJECTION SITE PAIN	2	24SEP2020	1/8	2	Yes		NA	R (01OCT2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1005 10051199	3^		Pain/ BODY ACHES	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	03SEP2020	1/3	2	Yes		NA/TC	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11005 10051200	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	24SEP2020	1/3	2	Yes		NA/TC	R (26SEP2020)	N/N
		GENRL	Chills/ BODY CHILLS	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N
		GASTR	Diarrhoea/ LOOSE STOOL	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Chills/ CHILLS	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
			Pyrexia/ FEVER	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	1	04SEP2020	2/3	1	Yes		NA/TC	R (06SEP2020)	N/N
		INFEC	Gastroenteritis/ GASTROENTERITIS	1	19SEP2020	17/1	2	No	O	NA	R (19SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100	3^	GENRL	Pain/ BODY ACHES	2	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N
			Fatigue/ FATIGUE	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1005 10051210		MUSC	Myalgia/ MYALGIA	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1005 10051216	3^	GASTR	Diarrhoea/ DIARRHEA	2	27SEP2020	4/C	1	Yes		NA/TC	N	N/N
16-55/ C459100 1 1005 10051217	3^	GENRL	Feeling hot/ CALOR	1	04SEP2020	2/1	1	Yes		NA	R (04SEP2020)	N/N
			Injection site pain/ PAIN AT INJECTION SITE	1	04SEP2020	2/3	2	Yes		NA	R (06SEP2020)	N/N
		RESP	Oropharyngeal pain/ SORE THROAT	1	05SEP2020	3/1	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1005 10051219	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		RENAL	Pollakiuria/ INCREASED FREQUENCY OF URINATION	1	04SEP2020	2/4	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C459100 1 1006 10061023	3^	INJ&P	Bone contusion/ RIGHT HIP BONE CONTUSION	1	28AUG2020	17/8	2	No	O	NA/TC	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1006 10061031	3^	INFEC	Oral fungal infection/ ORAL YEAST INFECTION	1	16AUG2020	4/11	2	No	O	NA/TC	R (26AUG2020)	N/N
16-55/ C459100 1 1006 10061032	3^	GENRL	Chills/ generalized chills	2	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
		MUSC	Myalgia/ generalized muscle aches	2	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 1 1006 10061040	3^	INFEC	Pharyngitis streptococcal/ Strep throat	2	08SEP2020	5/11	2	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1006 10061053	3^	NERV	Dizziness/ Lightheadedness	1	18AUG2020	1/9	2	Yes		NA	R (26AUG2020)	N/N
16-55/ C459100 1 1006 10061070	3^	NERV	Migraine/ Migraines - Intermittent	1	31AUG2020	13/C	3	No	O	NA	N	N/N
16-55/ C459100 1 1006 10061079	3^	GENRL	Chills/ CHILLS	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ FEVER	2	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Pain/ BODY ACHES- GENERALIZED	2	17SEP2020	2/3	2	Yes		NA	R (19SEP2020)	N/N
		BLOOD	Lymphadenopathy/ Enlarged cervical chain lymph nodes	2	29OCT2020	44/15	1	No	O	NA	R (12NOV2020)	N/N
16-55/ C459100 1 1006 10061089	3^	CARD	Tachycardia/ Tachycardia	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1006 10061090	3^	MUSC	Back pain/ BACK ACHE	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1006 10061093	3^	NERV	Paraesthesia/ FACIAL TINGLING	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
		SKIN	Rash/ CHEST RASH (8 cm)	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Pain/ GENERALIZED ACHES	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Pyrexia/ FEVER	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11006 10061094			Pain/ GENERALIZED ACHES	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Pyrexia/ FEVER	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100 11006 10061112	3^	GENRL	Chills/ Chills	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
		MUSC	Myalgia/ mUSCLE aCHES	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 11006 10061137	3^	GASTR	Nausea/ Nausea	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Pain/ Body aches	1	02SEP2020	2/1	3	Yes		NA/TC	R (02SEP2020)	N/N
16-55/ C459100 11006 10061144	3^	NERV	Headache/ Headache	1	22SEP2020	20/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 11006 10061151	3^	NERV	Headache/ Headache	2	05NOV2020	23/1	2	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C459100	3^	PSYCH	Attention deficit hyperactivity disorder/	2	02NOV2020	22/C	2	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1006 10061153			Attention Deficit Hyperactive Disorder									
16-55/ C459100 1 1006 10061160	3^	GASTR	Diarrhoea/ DIARRHEA	1	27SEP2020	3/3	2	Yes		NA/TC	R (29SEP2020)	N/N
			Vomiting/ VOMITING	1	27SEP2020	3/3	2	Yes		NA/TC	R (29SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	27SEP2020	3/3	2	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 1 1006 10061165	3^	GENRL	Pain/ Generalized Body Aches	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N
			Pyrexia/ Fever	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1006 10061166	3^	GENRL	Chills/ CHILLS	1	27SEP2020	3/2	2	Yes		NA	R (28SEP2020)	N/N
		GENRL	Pain/ Body Aches	2	16OCT2020	2/3	2	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1007 10071083	2^	RESP	Oropharyngeal pain/ sore throat	1	05AUG2020	9/2	1	No	O	NA	R (06AUG2020)	N/N
16-55/ C459100	2^	REPRO	Menorrhagia/ exacerbation of menorrhagia	2	06SEP2020	19/14	2	No	O	NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1007 10071087	2^	MUSC	Myalgia/ Right Scapular Muscle Pain	2	21AUG2020	2/12	3	No	O	NA/TC/TCN	R (01SEP2020)	N/N
1 1007 10071097		BLOOD	Lymphadenopathy/ Bilateral Swollen Cervical Lymph Nodes	2	23AUG2020	4/12	1	No	O	NA/TC	R (03SEP2020)	N/N
16-55/ C459100	3^	MUSC	Tendonitis/ Exacerbation of tendonitis	2	23SEP2020	28/C	2	No	O	NA/TCN	RG	N/N
1 1007 10071108												
16-55/ C459100	3^	PSYCH	Anxiety/ exacerbation of anxiety	2	07SEP2020	15/C	2	No	O	NA/TC	RG	N/N
1 1007 10071110												
16-55/ C459100	3^	NERV	Syncope/ fainting episode	1	11AUG2020	7/1	2	No	O	NA	R (11AUG2020)	N/N
1 1007 10071130												
16-55/ C459100	3^	GENRL	Vaccination site nodule/ nodule at vaccination site	2	27AUG2020	1/8	1	Yes		NA	R (03SEP2020)	N/N
1 1007 10071148												
16-55/ C459100	3^	GENRL	Injection site pain/ burning sensation at injection site	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y
1 1007 10071157												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1007 10071158	3^	GENRL	Injection site pain/ tenderness at injection site	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y
16-55/ C459100 1 1007 10071159	3^	BLOOD	Lymphadenopathy/ Left axilla enlarged lymph node	1	11AUG2020	2/2	1	Yes		NA/TC	R (12AUG2020)	N/N
16-55/ C459100 1 1007 10071172	3^	EAR	Ear discomfort/ Right ear pressure	2	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Malaise/ Malaise	2	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1007 10071181	3^	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	1	17AUG2020	6/8	1	No	O	NA	R (24AUG2020)	N/N
		SKIN	Rash/ generalized Rash	2	05SEP2020	4/7	2	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1007 10071186	3^	INFEC	Dermatitis infected/ Infected Atopic Dermatitis of the cheek	2	28SEP2020	26/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1007 10071194	3^	SKIN	Ecchymosis/ right foot ecchymosis	1	25AUG2020	13/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C459100	3^	GENRL	Fatigue/ fatigue	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Relative ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1007 10071203			Injection site pain/ injection site soreness	1	17AUG2020	1/2	1	Yes		NA/TC	R (18AUG2020)	N/N
16-55/ C459100 1 1007 10071207	3^	GENRL	Fatigue/ Fatigue	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ Fever	2	09SEP2020	2/2	1	Yes		NA/TC	R (10SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	09SEP2020	2/2	1	Yes		NA/TC	R (10SEP2020)	N/N
		RENAL	Dysuria/ intermittent dysuria	2	09SEP2020	2/26	2	No	O	NA/TC	R (04OCT2020)	N/N
			Pollakiuria/ intermittent urinary frequency	2	09SEP2020	2/26	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 1007 10071208	3^	INFEC	Viral infection/ viral illness	2	08SEP2020	1/C	1	No	O	NA	RG	N/N
		CARD	Palpitations/ heart palpitations	2	09SEP2020	2/C	1	No	O	NA/TC	RG	N/N
		GENRL	Chest pain/ Chest Pain	2	23SEP2020	16/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1007 10071218	3^	MUSC	Myalgia/ myalgia to neck and shoulder	1	21AUG2020	3/3	1	Yes		NA/TC	R (23AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1007 10071219	3^	INJ&P	Joint injury/ Left Knee Injury	1	09SEP2020	22/C	2	No	O	NA/TCN	RG	N/N
16-55/ C459100 1 1007 10071236	3^	MUSC	Myalgia/ left arm muscle pain*		20AUG2020	1/1	2	Yes		NA/TC	R (20AUG2020)	N/N
16-55/ C459100 1 1007 10071238	3^	SKIN	Rash/ rash	2	12SEP2020	3/17	1	No	O	NA	R (28SEP2020)	N/N
16-55/ C459100 1 1007 10071253	3^	GENRL	Injection site erythema/ redness at injection site	1	24AUG2020	1/2	2	Yes		NA	R (25AUG2020)	N/Y
			Injection site induration/ induration at injection site	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/Y
		GENRL	Injection site erythema/ redness at injection site	2	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C459100 1 1007 10071276	3^	BLOOD	Leukocytosis/ leukocytosis	2	24SEP2020	8/26	3	No	O	NA	R (19OCT2020)	N/N
			Thrombocytosis/ thrombocytosis	2	24SEP2020	8/33	3	No	O	NA	R (26OCT2020)	N/N
		NEOPL	Chronic myeloid leukaemia/ chronic myelogenous leukemia	2	24SEP2020	8/C	4	No	O	NA/TC	N	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1007 10071284	3^	GENRL	Injection site pain/ Right Arm Injection Site Pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	28AUG2020	2/2	2	Yes		NA	R (29AUG2020)	N/N
		SKIN	Rash/ rash on chest	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		RESP	Reflux laryngitis/ laryngopharyngeal reflux	2	02OCT2020	16/1	1	No	O	NA	R (02OCT2020)	N/N
16-55/ C459100 1 1007 10071289	3^	GENRL	Injection site erythema/ redness at injection	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/Y
		GENRL	Chills/ Chills	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
			Pain/ Bodyaches	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
			Pyrexia/ fever	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
		MUSC	Pain in extremity/ Left arm soreness	2	17SEP2020	1/7	1	Yes		NA	R (23SEP2020)	N/Y
		NERV	Headache/ Headache	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1007 10071295	3^	INJ&P	Fall/ Fall	2	03OCT2020	18/1	1	No	O	NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Skin laceration/ Laceration to left leg	2	03OCT2020	18/C	2	No	O	NA/TCN	RG	N/N
16-55/ C459100 1 1008 10081030	3^	INFECTION	Otitis media/ Right otitis media	2	24OCT2020	51/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1008 10081032	3^	MUSCULOSKELETAL	Synovitis/ Synovitis, right wrist(etiology unknown)	2	06OCT2020	23/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1008 10081064	3^	GENERAL	Chills/ chills	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Fatigue/ fatigue	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ fever	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1008 10081089	3^	GENERAL	Chills/ Chills	2	17SEP2020	3/1	2	Yes		NA	R (17SEP2020)	N/N
			Pain/ Body aches	2	17SEP2020	3/1	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1008 10081095	3^	GENERAL	Chills/ chills	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Fatigue/ fatigue	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1008 10081099	3^	INFE	Gastroenteritis/ gastroenteritis	2	03OCT2020	19/5	2	No	O	NA	R (07OCT2020)	N/N
16-55/ C459100 1 1008 10081138	3^	INJ&P	Skin laceration/ Finger laceration	1	06SEP2020	10/32	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1008 10081142	3^	GENRL	Pain/ Body aches	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1008 10081149	3^	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ Injection site pain left arm	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Pain/ Body aches	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1008 10081150			Pain/ Body aches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1008 10081155	3^	MUSC	Myalgia/ Generalized muscle aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		NERV	Headache/ Headache	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain Left deltoid	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
			Pain/ Body aches	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1008 10081159	3^	GENRL	Injection site pain/ Injection site pain left arm	2	22SEP2020	1/5	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1008 10081160	3^	GASTR	Diarrhoea/ Diarrhea	1	02SEP2020	2/6	1	Yes		NA	R (07SEP2020)	N/N
			Nausea/ Nausea	1	02SEP2020	2/6	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C459100	3^	GASTR	Diarrhoea/ Diarrhea	1	12SEP2020	11/4	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1008 10081166		GASTR	Diarrhoea/ Diarrhea	2	30SEP2020	8/4	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1008 10081183	3^	GENRL	Chills/ Chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1008 10081193	3^	GENRL	Pain/ body aches	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ chills	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1008 10081198	3^	GENRL	Fatigue/ Fatigue	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1008 10081215	3^	GENRL	Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1008 10081217	3^	CARD	Tachycardia/ Tachycardia	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1008 10081225	3^	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Pain/ Body aches	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1008 10081256	3^	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Pain/ Body aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1008 10081258	3^	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Pain/ Body aches	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	1/4	1	Yes		NA	R (04OCT2020)	N/N
		MUSC	Arthralgia/ Joint pain	2	01OCT2020	1/4	1	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 1008 10081260	3^	SKIN	Alopecia areata/ Alopecia areata	1	23SEP2020	15/C	1	Yes		NA	RG	N/N
16-55/ C459100	3^	GENRL	Pain/ Body aches	1	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1008 10081261		NERV	Headache/ Headaches	1	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
		GENRL	Chills/ Chills	2	01OCT2020	1/2	2	Yes		NA	R (02OCT2020)	N/N
			Pain/ Body aches	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N
			Pyrexia/ Fever	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		NERV	Headache/ Headache	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1008 10081271	3^	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Pain/ bodyaches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1008 10081289	3^	GENRL	Injection site pain/ Injection site pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Pain/ Body aches	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1008 10081293			Injection site pain/ Injection site pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
			Pain/ Body aches	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1008 10081314	3^	IN FEC	Urinary tract infection/ Urinary tract infection	1	30SEP2020	17/11	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1008 10081316	3^	GEN RL	Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
			Pain/ Body aches	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1008 10081321	3^	GEN RL	Pain/ Body aches	2	06OCT2020	2/5	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1008 10081327	3^	GEN RL	Chills/ Chills	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
			Pain/ Body aches	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N
			Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1008 10081333	3^	NERV	Headache/ Headache	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1008 10081337	3^	GENRL	Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1008 10081341	3^	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Pain/ Body aches	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1008 10081346	3^	NERV	Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		NERV	Headache/ Headache	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1008 10081346	3^	GENRL	Chills/ Chills	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1008 10081347	3^	GENRL	Injection site pain/ Injection site soreness	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
			Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/ Injection site soreness	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
			Pyrexia/ Fever	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
			Chills/ Chills	2	09OCT2020	2/2	2	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1008 10081348	3^	GENRL	Pyrexia/ Fever	2	09OCT2020	2/2	2	Yes		NA	R (10OCT2020)	N/N
			Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
			Pain/ Body aches	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
			Headache/ Headache	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1008 10081350	3^	INFEC	Gastroenteritis viral/ viral gastroenteritis	2	22OCT2020	15/3	2	No	O	NA	R (24OCT2020)	N/N
16-55/ C459100	3^	GASTR	Diarrhoea/ diarrhea	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1008 10081361	3^	GASTR	Diarrhoea/ Diarrhea	1	20SEP2020	5/1	1	Yes		NA	R (20SEP2020)	N/N
1 1008 10081364	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
1 1008 10081366		GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/N
		GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
			Pyrexia/ Fever	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		NERV	Migraine/ Migraine	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1008 10081367	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	08OCT2020	2/5	1	Yes		NA	R (12OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1008 10081384	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1008 10081388	3^	METAB	Decreased appetite/ Loss of appetite	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1008 10081391	3^	GASTR	Diarrhoea/ Diarrhea	1	30SEP2020	14/1	1	No	O	NA	R (30SEP2020)	N/N
			Nausea/ Nausea	1	30SEP2020	14/1	1	No	O	NA	R (30SEP2020)	N/N
			Vomiting/ Vomiting	1	30SEP2020	14/1	1	No	O	NA	R (30SEP2020)	N/N
		INFEC	Ear infection/ Left ear infection	2	31OCT2020	24/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1008 10081402	3^	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	2	10OCT2020	2/2	3	Yes		NA	R (11OCT2020)	N/N
			Fatigue/ Fatigue	2	10OCT2020	2/1	3	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1008 10081404	3^		Injection site erythema/ Injection site redness	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
			Injection site pain/ Injection site pain	2	10OCT2020	2/2	2	Yes		NA/TC	R (11OCT2020)	N/N
			Injection site swelling/ Injection site swelling	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
		METAB	Decreased appetite/ Loss of appetite	2	10OCT2020	2/2	2	Yes		NA	R (11OCT2020)	N/N
		PSYCH	Anxiety/ Anxiety episode	1	18SEP2020	1/1	2	Yes		NA/TCN	R (18SEP2020)	N/Y
		GENRL	Chills/ Chills	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1008 10081427	3^	GENRL	Injection site pain/ Injection site pain	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
			Injection site pain/ Injection site pain	1	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1008 10081435		NERV	Headache/ Headache	1	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N	
		GENRL	Fatigue/ Fatigue	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N	
			Injection site pain/ Injection site pain	2	12OCT2020	1/3	1	Yes		NA/TC	R (14OCT2020)	N/N	
		NERV	Headache/ Headache	2	12OCT2020	1/3	1	Yes		NA/TC	R (14OCT2020)	N/N	
		3^	INFEC	Tooth infection/ Tooth infection	2	07NOV2020	27/C	1	No	O	NA/TC	RG	N/N
		3^	GENRL	Chills/ Chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
				Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
		3^	INFEC	Sinusitis/ Sinus infection	2	01NOV2020	20/13	2	No	O	NA/TC	R (13NOV2020)	N/N
16-55/ C459100 1 1008 10081477	3^	GENRL	Pyrexia/ Fever(101.3 degrees fahrenheit)	2	14OCT2020	1/3	2	Yes		NA	R (16OCT2020)	N/N	
		MUSC	Myalgia/ Muscle pain	2	14OCT2020	1/3	2	Yes		NA	R (16OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1008 10081485	3^	GASTR	Nausea/ Nausea	2	14OCT2020	1/5	1	Yes		NA	R (18OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
			Injection site pain/ Injection site pain	2	14OCT2020	1/4	2	Yes		NA/TC	R (17OCT2020)	N/N
		NERV	Headache/ Headache	2	14OCT2020	1/2	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1008 10081492	3^	GASTR	Toothache/ Toothache	1	03OCT2020	11/5	1	No	O	NA/TC	R (07OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10NOV2020	2/4	1	Yes		NA	R (13NOV2020)	N/N
			Injection site erythema/ Injection site redness	2	10NOV2020	2/4	1	Yes		NA	R (13NOV2020)	N/N
			Injection site pain/ Injection site arm soreness	2	10NOV2020	2/4	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C459100 1 1008 10081496	3^	GASTR	Tooth impacted/ Impacted wisdom tooth	1	08OCT2020	16/1	2	No	O	NA/TC/TCN	R (08OCT2020)	N/N
16-55/ C459100 1 1008 10081497	3^	GASTR	Abdominal pain upper/ Upper abdominal pain	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1008 10081500	3^	GENRL	Pain/ Body aches	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Pain/ Body aches	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		GENRL	Pain/ Body aches	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1008 10081513	3^	GENRL	Pyrexia/ Fever	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1008 10081524	3^	GENRL	Chills/ Chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Pain/ Body aches	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1008 10081525	3^	GENRL	Injection site pain/ Injection site pain	1	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1008 10081533	3^	GENRL	Injection site pain/ Injection site pain	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C459100 1 1008 10081541	3^	GENRL	Injection site pain/ Injection site pain	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
		GENRL	Pain/ Body aches	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1008 10081549	3^	GENRL	Fatigue/ Fatigue	1	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1008 10081554	3^	GENRL	Injection site pain/ Injection site pain	1	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
			Chills/ Chills	2	20OCT2020	2/C	2	Yes		NA	N	N/N
			Pain/ Body aches	2	20OCT2020	2/C	2	Yes		NA/TC	N	N/N
			Pyrexia/ Fever	2	20OCT2020	2/C	2	Yes		NA/TC	N	N/N
16-55/ C459100 1 1008 10081554	3^	GENRL	Injection site pain/ injection site pain	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1008 10081557	3^	GENRL	Pain/ body aches	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
			Pyrexia/ fever	2	22OCT2020	2/1	2	Yes		NA	R (22OCT2020)	N/N
			Injection site pain/ injection site pain	2	23OCT2020	2/8	2	Yes		NA	R (30OCT2020)	N/N
			Fatigue/ fatigue	2	24OCT2020	3/7	2	Yes		NA	R (30OCT2020)	N/N
			Pain/ bodyaches	2	24OCT2020	3/7	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C459100 1 1008 10081567	3^	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
			Chills/ Chills	2	27OCT2020	1/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1008 10081572	3^	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/3	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1008 10081577	3^	GENRL	Injection site pain/ Injection site pain	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	1	13OCT2020	5/3	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1008 10081578			Fatigue/ Fatigue	1	13OCT2020	5/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1008 10081579	3^	GENRL	Injection site pain/ Injection site pain	1	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1008 10081580	3^	GENRL	Fatigue/ Fatigue	1	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
		MUSC	Myalgia/ Muscle aches	1	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1008 10081581	3^	GENRL	Injection site pain/ Injection site pain	1	10OCT2020	2/5	1	Yes		NA	R (14OCT2020)	N/N
			Injection site pruritus/ Injection site itching	1	10OCT2020	2/8	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1009 10091079	3^	SKIN	Dermal cyst/ CYST ON FOREHEAD	1	28AUG2020	9/15	1	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1009 10091080	3^	INFEC	Nasopharyngitis/ HEAD COLD	2	03OCT2020	24/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1009 10091088	3^	GENRL	Chills/ CHILLS	2	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1009 10091108	3^	GENRL	Injection site pain/ pain at injection site	2	15SEP2020	1/4	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	16SEP2020	2/C	1	Yes		NA	RG	N/N
		MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	16SEP2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1009 10091109	3^	NERV	Dysgeusia/ Metallic Taste In Mouth Following Vaccination	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/Y
16-55/ C459100 1 1009 10091110	3^	GASTR	Aphthous ulcer/ CANKER SORES	2	07OCT2020	24/C	2	No	O	NA/TC	RG	N/N
		INFEC	Gingivitis/ RIGHT UPPER MOUTH GUM INFECTION	2	07OCT2020	24/C	2	No	O	NA	RG	N/N
16-55/ C459100 1 1009 10091112	3^	MUSC	Myalgia/ generalized muscle aches	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100	3^	MUSC	Myalgia/ generalized muscle soreness	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1009 10091116		INJ&P	Concussion/ CONCUSSION	2	23OCT2020	37/C	2	No	O	NA/TC	RG	N/N
			Fall/ FALL	2	23OCT2020	37/1	2	No	O	NA	R (23OCT2020)	N/N
			Muscle strain/ NECK MUSCLE STRAIN	2	23OCT2020	37/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1009 10091117	3^	GENRL	Chills/ chills	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ generalized muscle soreness	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1009 10091129	3^	GENRL	Axillary pain/ LEFT AXILLA TENDERNESS	2	17SEP2020	2/19	1	Yes		NA/TC	R (05OCT2020)	N/N
			Chills/ CHILLS	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
			Fatigue/ FATIGUE	2	17SEP2020	2/6	1	Yes		NA	R (22SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	17SEP2020	2/8	1	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN, GENERALIZED	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1009 10091138	3^	GENRL	Chills/ CHILLS	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Fatigue/ fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1009 10091142	3^	INJ&P	Limb traumatic amputation/ ACCIDENTAL LEFT THUMB FINGER TIP AMPUTATION	1	07SEP2020	7/C	2	No	O	NA/TC/TCN	RG	N/N
		RESP	Oropharyngeal pain/ SORE THROAT	1	11SEP2020	11/2	1	No	O	NA	R (12SEP2020)	N/N
		GENRL	Chills/ chills	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
			Fatigue/ fatigue	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ generalized muscle aches	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1009 10091166	3^	REPRO	Breast cyst/ Left Breast Cysts	1	17SEP2020	8/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1009 10091171	3^	MUSC	Back pain/ WORSENING LOWER BACK PAIN	1	15SEP2020	5/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pain in extremity/ BILATERAL LEG PAIN	1	15SEP2020	5/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1009 10091175	3^	GENRL	Chills/ chills	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
			Injection site pain/ soreness at injection site	1	15SEP2020	2/6	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Chills/ chills	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		MUSC	Myalgia/ generalized muscle pain	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1009 10091194	3^	INFEC	Bacterial vulvovaginitis/ Vaginal Bacterial Infection	1	30SEP2020	7/19	2	No	O	NA/TC	R (18OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	16OCT2020	2/3	2	Yes		NA/TC	R (18OCT2020)	N/N
			Injection site pain/ muscle pain at injection site	2	16OCT2020	2/3	2	Yes		NA/TC	R (18OCT2020)	N/N
		NERV	Headache/ headache	2	16OCT2020	2/3	2	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1011 10111035	3^	GENRL	Fatigue/ Fatigue	1	19AUG2020	6/4	1	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1011 10111039	3^	GENRL	Injection site erythema/ Injection site redness	1	14AUG2020	1/9	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C459100 1 1011 10111046	3^	GENRL	Injection site bruising/ Bruise on left arm around the injection site	1	18AUG2020	2/5	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Pyrexia/ Fever 101.4	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Aches	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Chills/ Chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1011 10111070	3^	EYE	Eye pruritus/ Itchy Eyes	1	15SEP2020	28/10	1	No	O	NA	R (24SEP2020)	N/N
		RESP	Nasal congestion/ Nasal Congestion	1	15SEP2020	28/10	1	No	O	NA	R (24SEP2020)	N/N
		RESP	Respiratory tract congestion/ Chest Congestion	1	25SEP2020	38/4	1	No	O	NA	R (28SEP2020)	N/N
16-55/ C459100 1 1011 10111071	3^	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Chills/ Chills	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1011 10111079	3^	MUSC	Pyrexia/ Fever 100.6	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
			Myalgia/ Generalized myalgia	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Chills/ Chills	2	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N
			Fatigue/ Fatigue	2	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N
			Pyrexia/ Fever 101.9	2	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N
NERV	Headache/ Headache	2	10SEP2020	1/6	1	Yes		NA/TC	R (15SEP2020)	N/N		
16-55/ C459100 1 1011 10111088	3^	INFEC	Oral candidiasis/ Oral Thrush	1	03SEP2020	11/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1011 10111107	3^	GENRL	Chills/ Chills	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ Fever 101.5	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ Generalized myalgia	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11011 10111116	3^	INFEC	Labyrinthitis/ Inner Ear Infection	1	17SEP2020	22/9	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C459100 11011 10111117	3^	GENRL	Chills/ Chills	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
			Fatigue/ Fatigue	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
			Pyrexia/ Fever 101.0	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 11011 10111118	3^	MUSC	Myalgia/ Left shoulder muscle pain	2	28SEP2020	11/C	1	Yes		NA/TC	N	N/N
			Myalgia/ Muscle pain left side of neck	2	28SEP2020	11/C	1	Yes		NA/TC	N	N/N
16-55/ C459100 11011 10111123	3^	GENRL	Chills/ Chills	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ Fever 100.7	2	19SEP2020	2/1	1	Yes		NA/TC	RS (19SEP2020)	N/N
		MUSC	Myalgia/ Generalized myalgia	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1011 10111125			Pyrexia/ Fever	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ Generalized myalgia	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1011 10111129	3^	NERV	Headache/ Headache	2	21SEP2020	1/1	2	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1011 10111154	3^	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ Fever 100.4	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Aches	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1011 10111170	3^	GENRL	Chills/ Chills	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
			Pyrexia/ Fever 100.00	2	29OCT2020	1/2	1	Yes		NA/TC	R (30OCT2020)	N/N
		NERV	Headache/ Headache	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1012 10121058												
16-55/ C459100	3^	INJ&P	Ligament sprain/ Left Ankle Sprain	1	30SEP2020	38/C	1	No	CND	NA/TC	RG	N/N
1 1012 10121065												
16-55/ C459100	3^	GENRL	Chills/ CHILLS	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
1 1012 10121073												
			Injection site pain/ RIGHT ARM INJECTION SITE PAIN	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		PSYCH	Insomnia/ INSOMNIA	2	14SEP2020	1/1	2	Yes		NA	R (14SEP2020)	N/N
		HEPAT	Cholelithiasis/ Cholelithiasis	2	28SEP2020	15/C	2	No	CND	NA/TC	N	N/N
16-55/ C459100	3^	NERV	Headache/ Intermittent Headaches	2	23SEP2020	9/C	1	No	CND	NA	RG	N/N
1 1012 10121079												
16-55/ C459100	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
1 1012 10121085												
		GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1012 10121087	3^	GENRL	Injection site pain/ Left Arm Injection Site Pain	2	25SEP2020	1/4	2	Yes		NA	R (28SEP2020)	N/N	
			Pyrexia/ Fever	2	25SEP2020	1/34	2	Yes		NA	R (28OCT2020)	N/N	
			Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N	
			Fatigue/ FATIGUE	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
			Pain/ BODY ACHES	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N	
16-55/ C459100 1 1012 10121095	3^	GENRL	Pyrexia/ FEVER	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N	
			MUSC	Arthralgia/ JOINT PAIN	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
			NERV	Fatigue/ Fatigue	1	07SEP2020	8/8	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C459100 1 1012 10121096	3^	INFEC	Dizziness/ Lightheadedness	1	07SEP2020	8/3	1	Yes		NA	R (09SEP2020)	N/N	
			Ear infection/ Bilateral Ear Infection	1	01SEP2020	2/10	2	No	O	NA/TC	R (10SEP2020)	N/N	
16-55/ C459100	3^	GENRL	Injection site pain/ RIGHT ARM INJECTION SITE PAIN	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1012 10121101		GENRL	Injection site pain/ Right Arm Injection Site Pain	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1012 10121103	3^	PSYCH	Anxiety/ ANXIETY	2	22SEP2020	1/C	1	No	O	NA	N	N/Y
			Post-traumatic stress disorder/ POST TRAUMATIC STRESS DISORDER	2	22SEP2020	1/C	1	No	O	NA	N	N/Y
16-55/ C459100 1 1012 10121105	3^	GENRL	Injection site swelling/ Right arm localized swelling at injection site	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N
		NERV	Headache/ Headache	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Injection site discolouration/ Right arm hyperpigmentation at injection site	1	05SEP2020	5/C	1	Yes		NA	RG	N/N
		GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Injection site discolouration/ Hyperpigmentation at Injection Site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ PAIN AT INJECTION SITE	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Injection site swelling/ Swelling at Injection Site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1012 10121108	3^	GASTR	Diarrhoea/ Diarrheal Episode	1	15SEP2020	15/1	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C459100 1 1012 10121111	3^	GASTR	Nausea/ NAUSEA	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Chills/ CHILLS	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
			Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
			Pyrexia/ FEVER	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		GASTR	Nausea/ NAUSEA	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ FEVER	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1012 10121118	3^	SURG	Dental implantation/ Dental Implant Right Upper Molar	2	15OCT2020	25/1	1	No	CND	NA/TC	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1012 10121121	3^	GENRL	Pyrexia/ FEVER	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		ENDO	Basedow's disease/ GRAVE'S DISEASE	2	08OCT2020	18/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1012 10121131	3^	GASTR	Nausea/ NAUSEA	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
			Fatigue/ FATIGUE	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ FEVER	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1012 10121132	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Chills/ Body Chills	2	23SEP2020	1/2	3	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	2/C	2	Yes		NA/TC	RG	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Left Arm Injection Site Pain	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1012 10121137		EYE	Diplopia/ Double Vision	2	26SEP2020	2/2	1	No	CND	NA	R (27SEP2020)	N/N
		GENRL	Injection site pain/ Left Arm Injection Site Pain	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
			Pyrexia/ Fever	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C459100 1 1012 10121145	3^	GASTR	Nausea/ Nausea	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
			Vomiting/ Vomiting	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
		GENRL	Pain/ Body Aches	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
			Pyrexia/ Fever	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ Headache	2	25SEP2020	1/C	2	Yes		NA	RG	N/N
16-55/ C459100 1 1012 10121146	3^	MUSC	Myalgia/ MUSCLE ACHES	1	05SEP2020	1/4	2	Yes		NA/TC	R (08SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	2	28SEP2020	1/3	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Arm Pain at Injection Site	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1012 10121154	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
1 1012 10121162		GASTR	Nausea/ NAUSEA	2	02OCT2020	2/1	2	Yes		NA	R (02OCT2020)	N/N
		GENRL	Pyrexia/ FEVER	2	02OCT2020	2/32	1	Yes		NA	R (02NOV2020)	N/N
		NERV	Headache/ HEADACHE	2	02OCT2020	2/32	2	Yes		NA/TC	R (02NOV2020)	N/N
16-55/ C459100	3^	GENRL	Injection site dermatitis/ LEFT UPPER ARM DERMATITIS AT INJECTION SITE	1	11SEP2020	3/C	2	Yes		P/W	RG	N/N
1 1012 10121163		PSYCH	Insomnia/ INSOMNIA	1	12SEP2020	4/C	2	Yes		NA/TC	N	N/N
		INV	Weight decreased/ WEIGHT LOSS	1	14SEP2020	6/21	3	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100	3^	EAR	Vertigo/ Vertigo	2	21OCT2020	20/4	1	No	O	NA	R (24OCT2020)	N/N
1 1012 10121172												
16-55/ C459100	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
1 1012 10121173												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1012 10121174	3^	GENRL	Chills/ CHILLS	2	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N
		GENRL	Injection site pain/ LOCALIZED LEFT ARM PAIN AT INJECTION SITE	1	11SEP2020	2/4	2	Yes		NA	R (14SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	01OCT2020	2/1	2	Yes		NA	R (01OCT2020)	N/N
			Fatigue/ FATIGUE	2	01OCT2020	2/1	2	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
			Pain/ BODY ACHES	2	01OCT2020	2/1	2	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ FEVER	2	01OCT2020	2/1	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1012 10121178	3^	NERV	Headache/ HEADACHE	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N
			Fatigue/ FATIGUE	2	08OCT2020	1/C	1	Yes		NA	RG	N/N
			Pain/ BODY ACHES	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1012 10121182	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
			Chills/ CHILLS	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
			Fatigue/ FATIGUE	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
			Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N
			Pain/ BODY ACHES	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
		GENRL	Pyrexia/ FEVER	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1012 10121183	3^	GENRL	Chills/ CHILLS	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
			Chills/ CHILLS	2	03OCT2020	2/1	2	Yes		NA	R (03OCT2020)	N/N
			Arthralgia/ JOINT PAIN	2	03OCT2020	2/1	2	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1012 10121187	3^	NERV	Paraesthesia/ Left Shoulder Tingling	2	23OCT2020	22/3	1	No	O	NA	R (25OCT2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/1	2	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1012 10121188			Pyrexia/ Fever	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1013 10131003	2^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	28JUL2020	1/11	1	Yes		NA	R (07AUG2020)	N/N
		GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	09AUG2020	13/4	1	Yes		NA	R (12AUG2020)	N/N
16-55/ C459100 1 1013 10131006	2^	MUSC	Myalgia/ MUSCLE PAIN	1	04AUG2020	8/1	2	Yes		NA	R (04AUG2020)	N/N
16-55/ C459100 1 1013 10131014	2^	GENRL	Fatigue/ FATIGUE	1	31JUL2020	3/6	1	Yes		NA	R (05AUG2020)	N/N
16-55/ C459100 1 1013 10131015	2^	GASTR	Diarrhoea/ DIARRHEA	1	29JUL2020	1/8	1	Yes		NA	R (05AUG2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	29JUL2020	1/8	2	Yes		NA	R (05AUG2020)	N/N
16-55/ C459100 1 1013 10131021	2^	GASTR	Diarrhoea/ DIARRHEA	1	13AUG2020	15/9	2	No	O	NA	R (21AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131032	2^	NERV	Headache/ HEADACHE	1	05AUG2020	7/2	1	Yes		NA	R (06AUG2020)	N/N
16-55/ C459100 1 1013 10131051	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	03AUG2020	1/4	1	Yes		NA	R (06AUG2020)	N/Y
		NERV	Headache/ HEADACHE	1	04AUG2020	2/5	1	Yes		NA	R (08AUG2020)	N/N
		INJ&P	Skin laceration/ LACERATION TO LEFT EYEBROW	2	01OCT2020	38/7	1	No	O	NA/TCN	R (07OCT2020)	N/N
16-55/ C459100 1 1013 10131055	3^	MUSC	Arthralgia/ PAIN RIGHT SHOULDER	2	25AUG2020	2/3	2	Yes		NA/TC	R (27AUG2020)	N/N
		INFEC	Tooth abscess/ TOOTH ABSCESS	2	20OCT2020	58/16	1	No	O	NA/TC	R (04NOV2020)	N/N
16-55/ C459100 1 1013 10131059	3^	GENRL	Fatigue/ FATIGUE	2	26AUG2020	2/1	3	Yes		NA	R (26AUG2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	26AUG2020	2/1	2	Yes		NA	R (26AUG2020)	N/N
16-55/ C459100 1 1013 10131067	3^	NERV	Headache/ HEADACHE	1	08AUG2020	5/4	1	Yes		NA	R (11AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131068	3^	INFEC	Otitis media/ left middle ear infection	1	15AUG2020	12/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1013 10131072	3^	MUSC	Myalgia/ muscle pain left hip	1	05AUG2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1013 10131084	3^	GENRL	Vascular stent occlusion/ OBSTRUCTED RENAL STENT (ARTERY)	2	01SEP2020	7/C	2	No	O	NA	RG	Y/N
16-55/ C459100 1 1013 10131112	3^	GENRL	Chills/ CHILLS	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
			Pain/ BODY ACHES	2	22SEP2020	1/4	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1013 10131113	3^	PSYCH	Depression/ Recurrence of depression.	2	15SEP2020	15/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1013 10131124	3^	VASC	Hypertension/ HYPERTENSION	1	20AUG2020	10/C	1	No	O	NA/TC	RG	N/N
		MUSC	Bursitis/ BURSITIS LEFT SHOULDER	1	28AUG2020	18/1	1	No	O	NA/TC	R (28AUG2020)	N/N
16-55/ C459100	3^	EAR	Ear discomfort/ ear discomfort	1	26AUG2020	16/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1013 10131125	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
1 1013 10131204	3^	GENRL	Chills/ CHILLS	2	10SEP2020	2/1	2	Yes		NA	RS (10SEP2020)	N/N
1 1013 10131207			Fatigue/ FATIGUE	2	10SEP2020	2/3	2	Yes		NA	R (12SEP2020)	N/N
			Pain/ BODY ACHES	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
			Pyrexia/ FEVER	2	10SEP2020	2/8	2	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Pain/ body aches	2	14SEP2020	6/2	3	Yes		NA	R (15SEP2020)	N/N
		VASC	Deep vein thrombosis/ DEEP VEIN THROMBOSIS RIGHT POPTIAL VEIN	2	23SEP2020	15/6	3	No	O	NA/TC	RS (28SEP2020)	N/N
16-55/ C459100 1 1013 10131209	3^	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1013 10131215	3^	GENRL	Injection site bruising/ 1/2 CM BY 1/2 CM BRUISE AT INJECTION SITE	1	18AUG2020	1/13	1	Yes		NA	R (30AUG2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131218	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	10SEP2020	2/3	2	Yes		NA/TC	R (12SEP2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1013 10131221	3^	NERV	Headache/ FRONTAL HEADACHES	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1013 10131225	3^	GENRL	Chills/ CHILLIS	2	11SEP2020	3/2	1	Yes		NA	R (12SEP2020)	N/N
			Pain/ BODY ACHES	2	11SEP2020	3/2	1	Yes		NA/TC	R (12SEP2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	11SEP2020	3/2	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1013 10131231	3^	GENRL	Fatigue/ FATIGUE	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1013 10131239	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	2/1	2	Yes		NA/TC	R (20AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131245	3^	GENRL	Fatigue/ FATIGUE	2	09OCT2020	30/2	1	No	O	NA	R (10OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	14SEP2020	5/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1013 10131251	3^	GENRL	Pyrexia/ FEVER	2	14SEP2020	5/2	2	Yes		NA/TC	R (15SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	09SEP2020	2/4	2	Yes		NA/TC	R (12SEP2020)	N/N
		MUSC	Arthralgia/ JOINT PAIN	2	09SEP2020	2/4	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1013 10131258	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	2/5	1	Yes		NA	R (25AUG2020)	N/N
		GENRL	Chills/ CHILLS	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ LOW GRADE FEVER	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1013 10131259	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1013 10131264	3^	INV	Blood pressure increased/ ELEVATED BLOOD PRESSURE	2	11SEP2020	2/4	1	No	O	NA	R (14SEP2020)	N/N
16-55/ C459100 1 1013 10131268	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	22AUG2020	3/3	2	Yes		NA	R (24AUG2020)	N/N
16-55/ C459100 1 1013 10131271	3^	NERV	Headache/ HEADACHE	2	17SEP2020	1/8	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site swelling/ SWELLING AT INJECTION SITE	2	24SEP2020	8/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1013 10131276	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N
			Pain/ BODY ACHES	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1013 10131280		GENRL	Chills/ INTERMITTENT CHILLS	2	16SEP2020	1/4	2	Yes		NA	RS (19SEP2020)	N/N
			Pyrexia/ INTERMITTENT LOW GRADE FEVER	2	16SEP2020	1/4	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1013 10131283	3^	GENRL	Pain/ BODY ACHES	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1013 10131285	3^	GASTR	Abdominal pain/ ABDOMINAL PAIN	1	26AUG2020	3/2	3	No	O	NA/TC	R (27AUG2020)	N/N
		GENRL	Chills/ CHILLS	1	26AUG2020	3/2	1	Yes		NA/TC	R (27AUG2020)	N/N
16-55/ C459100 1 1013 10131287	3^	GENRL	Pyrexia/ FEVER	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1013 10131293	3^	GENRL	Chills/ CHILLS	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
			Pain/ BODY ACHES	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131299	3^	GENRL	Chills/ CHILLS	2	18SEP2020	4/2	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1013 10131303	3^	GENRL	Injection site haematoma/ INJECTION SITE HEMATOMA	2	18SEP2020	2/19	2	Yes		NA	R (06OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	19OCT2020	33/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1013 10131304	3^	GENRL	Fatigue/ FATIGUE	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
			Pain/ BODY ACHES	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1013 10131305	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	20SEP2020	4/4	2	Yes		NA/TC	R (23SEP2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	20SEP2020	4/2	2	Yes		NA/TC	R (21SEP2020)	N/N
16-55/ C459100 1 1013 10131318	3^	SKIN	Ingrowing nail/ RIGHT BIG TOE INGROWN TOE TAIL	1	04SEP2020	10/8	1	No	O	NA	R (11SEP2020)	N/N
16-55/ C459100 1 1013 10131338	3^	GENRL	Chills/ CHILLS	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)		
16-55/ C459100 1 1013 10131348	3^	GASTR	Vomiting/ VOMITING	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N		
		GENRL	Pyrexia/ LOW GRADE FEVER	2	18SEP2020	2/2	2	Yes		NA/TC	R (19SEP2020)	N/N		
		NERV	Headache/ HEADACHE	2	18SEP2020	2/3	2	Yes		NA/TC	R (20SEP2020)	N/N		
		GENRL	Chills/ CHILLS	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N		
			Pyrexia/ FEVER	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N		
		16-55/ C459100 1 1013 10131349	3^	INJ&P	Procedural pain/ RIGHT ARM SORENESS SECONDARY TO INJECTION	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
		16-55/ C459100 1 1013 10131355	3^	GENRL	Chills/ CHILLS	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
			Pain/ BODY ACHES	2	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N		
16-55/ C459100 1 1013 10131357	3^	GENRL	Chills/ CHILLS	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N		
	Fatigue/ FATIGUE	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N				

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131361	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	21SEP2020	1/4	2	Yes		NA/TC	R (24SEP2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N
			MUSC Arthralgia/ JOINT PAIN	2	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N
			Chills/ CHILLS	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1013 10131365	3^	INFEC	Sinusitis/ SINUS INFECTION	1	16SEP2020	17/C	1	No	O	NA/TC	RG	N/N
		MUSC	Myalgia/ MILD MUSCLE ACHES	2	25SEP2020	5/3	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	25SEP2020	5/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1013 10131371	3^	GASTR	Nausea/ NAUSEA	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Pain/ BODY ACHES	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1013 10131377	3^	GENRL	Chills/ CHILLS	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131385	3^	SKIN	Fatigue/ FATIGUE	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
			Pain/ LEFT UPPER BODY PAIN	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
			Rash/ RASH TO UPPER EXTREMITIES	2	26SEP2020	4/2	2	Yes		NA/TC	R (27SEP2020)	N/N
			Rash/ RASH TO UPPER TORSO	2	26SEP2020	4/2	2	Yes		NA/TC	R (27SEP2020)	N/N
			Rash/ RASH TO LOWER EXTREMITIES	2	27SEP2020	5/1	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C459100 1 1013 10131388	3^	NERV	Tension headache/ TENSION HEADACHE	1	10SEP2020	10/2	2	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1013 10131391	3^	MUSC	Muscle tightness/ MUSCLE TIGHTNESS	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1013 10131395	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	9/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	22SEP2020	2/3	2	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131405	3^	GENRL	Pyrexia/ LOW GRADE FEVER	2	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	3/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1013 10131406	3^	GENRL	Pyrexia/ LOW GRADE FEVER	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Intervertebral disc degeneration/ MILD L5-S1 DISC DEGENERATION	1	13SEP2020	12/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1013 10131409	3^	NERV	Dizziness/ LIGHTHEADEDNESS	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100	3^	NERV	Headache/ HEADACHE	1	02SEP2020	1/1	1	Yes		NA/TC	R (02SEP2020)	N/N
			Lethargy/ LETHARGIC	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N
			Dizziness/ LIGHTHEADEDNESS	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
			Headache/ HEADACHE	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/Y
			Lethargy/ LETHARGIC	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1013 10131416		GENRL	Chills/ CHILLS	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
			Pain/ BODY ACHES	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	03SEP2020	2/1	2	Yes		NA/TC	R (03SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
			Pain/ BODY ACHES	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N
		16-55/ C459100 1 1013 10131419	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	02SEP2020	1/2	1	Yes		NA
	NERV	Headache/ HEADACHE	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Malaise/ MALAISE	1	07SEP2020	6/10	1	Yes		NA	R (16SEP2020)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ HEADACHE	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1013 10131423	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1013 10131424	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	2/3	2	Yes		NA/TC	R (06SEP2020)	N/N
			Pain/ BODY ACHES	1	04SEP2020	2/3	2	Yes		NA/TC	R (06SEP2020)	N/N
16-55/ C459100 1 1013 10131427	3^	SKIN	Pruritus/ ITCHING ON ARMS AND LEGS	1	08SEP2020	6/26	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1013 10131438	3^	GENRL	Chills/ CHILLS	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1013 10131445	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131448	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	02OCT2020	2/3	2	Yes		NA/TC	R (04OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	02OCT2020	2/2	2	Yes		NA/TC	R (03OCT2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	28SEP2020	1/4	2	Yes		NA/TC	R (01OCT2020)	N/N
			Pyrexia/ FEVER	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
		GASTR	Nausea/ NAUSEA	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1013 10131451	3^	GENRL	Fatigue/ FATIGUE	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1013 10131463	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	28SEP2020	21/1	1	Yes		NA/TC	R (28SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1013 10131469	3^	GASTR	Nausea/ NAUSEA	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
1 1013 10131470		GENRL	Fatigue/ FATIGUE	1	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
1 1013 10131472		GENRL	Chills/ CHILLS	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Pain/ BODY ACHES	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
			Pain/ BODY ACHES	1	30SEP2020	22/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	28SEP2020	1/C	2	Yes		NA/TC	RG	N/N
1 1013 10131476		GENRL	Chills/ CHILLS	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
			Pain/ BODY ACHES	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131486	3^	GENRL	Injection site pain/ INJECTION PAIN	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION PAIN	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/Y
16-55/ C459100 1 1013 10131492	3^	GENRL	Injection site pain/ INJECTION PAIN	1	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1013 10131493	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N
		MUSC	Arthralgia/ LEFT SHOULDER PAIN	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA	2	30SEP2020	3/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1013 10131499	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/Y
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131500	3^	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1013 10131507	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1013 10131513	3^	NERV	Headache/ HEADACHE	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1013 10131514	3^	GENRL	Chills/ CHILLS	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
		GENRL	Pyrexia/ LOW GRADE FEVER	1	12SEP2020	3/1	1	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION PAIN	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	02OCT2020	3/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1013 10131515	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131518	3^	SKIN	Rash erythematous/ 2 RASH ON CHEST (PRURITIS AND REDDENED)	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1013 10131529	3^	NERV	Headache/ HEADACHE	1	15SEP2020	2/15	1	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C459100 1 1013 10131533	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ FEVER	1	16SEP2020	2/3	2	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1013 10131534	3^	GENRL	Chills/ Chills	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
			Pain/ BODY ACHES	1	16SEP2020	2/4	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1013 10131546	3^	GENRL	Chills/ CHILLS	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ HEADACHE	2	07OCT2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1013 10131553	3^	METAB	Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2	20OCT2020	15/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1013 10131556	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	06OCT2020	2/4	1	Yes		NA/TC	R (09OCT2020)	N/N
			Pyrexia/ Fever	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N
		NERV	Headache/ Headache	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1013 10131557	3^	INJ&P	Ligament sprain/ ANKLE SPRAIN RIGHT	1	26SEP2020	11/17	2	No	O	NA/TC	R (12OCT2020)	N/N
16-55/ C459100 1 1013 10131563	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1013 10131567	3^	GENRL	Fatigue/ FATIGUE	1	17SEP2020	1/5	2	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131568	3 [^]	GENRL	Fatigue/ FATIGUE	1	18SEP2020	2/3	2	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ ACHING UPPER BODY MUSCLES BILATERAL ARMS	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
			Myalgia/ ACHING UPPER BODY MUSCLES BILATERAL SHOULDERS	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1013 10131569	3 [^]	GENRL	Injection site pain/ MUSCLE SORENESS AT INJECTION SITE	1	18SEP2020	2/4	2	Yes		NA	R (21SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
		NERV	Dizziness/ DIZZINESS	2	28OCT2020	21/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1013 10131571	3 ^{^†}	GENRL	Injection site pain/ PAIN INJECTION SITE	2	07OCT2020	1/3	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1013 10131580	3 [^]	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131581	3^	NERV	Headache/ Headache	1	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
			Pain/ BODY ACHES	2	07OCT2020	2/4	1	Yes		NA	R (10OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	07OCT2020	2/4	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
			Pyrexia/ FEVER	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		16-55/ C459100 1 1013 10131599	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	21SEP2020	1/3	2	Yes		NA
GENRL	Injection site pain/ PAIN AT INJECTION SITE	2		12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131601	3 [^]	RESP	Nasal congestion/ NASAL CONGESTION	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1013 10131603	3 [^]	GENRL	Fatigue/ FATIGUE	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1013 10131607	3 [^]	RESP	Oropharyngeal pain/ SORE THROAT	1	25SEP2020	4/2	1	Yes		NA	R (26SEP2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA	1	28SEP2020	7/2	1	Yes		NA/TC	R (29SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	1	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1013 10131612	3 [^]	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100	3 ^{^†}	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1013 10131614		GENRL	Fatigue/ FATIGUE	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1013 10131633	3^	GENRL	Pain/ BODY ACHES	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ LOW GRADE FEVER	1	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1013 10131637	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	06OCT2020	1/C	1	Yes		NA	RG	N/N
		MUSC	Arthralgia/ JOINT PAIN	1	06OCT2020	1/C	1	Yes		NA	RG	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
		GENRL	Injection site swelling/ INJECTION SITE SWELLING	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C459100 1 1013 10131643	3^	NERV	Headache/ FRONTAL HEADACHE	1	06OCT2020	1/2	2	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131645	3^	PSYCH	Insomnia/ INSOMNIA	1	06OCT2020	1/2	2	Yes		NA	R (07OCT2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		MUSC	Arthralgia/ GENERALIZED JOINT PAIN	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
				2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		GENRL	Pain/ BODY ACHES	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1013 10131657	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1013 10131664	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1013 10131666	3^	INJ&P	Ligament rupture/ TORN LIGAMENTS TO LEFT FOOT	1	09OCT2020	2/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100	3^	MUSC	Pain in extremity/ Leg pain	2	05SEP2020	2/2	1	No	O	NA	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1015 10151015	3^	NERV	Syncope/ syncope*		14AUG2020	1/1	1	No	O	NA/TCN	R (14AUG2020)	N/N
1 1015 10151017	3^	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	8/1	1	Yes		NA	R (21AUG2020)	N/N
1 1015 10151023	3^	BLOOD	Lymphadenopathy/ Swollen lymph node - left armpit axillary	2	04SEP2020	1/5	1	Yes		NA	R (08SEP2020)	N/N
1 1015 10151041	3^	GASTR	Abdominal pain upper/ Stomach cramps	1	08SEP2020	23/2	1	No	CD	NA	R (09SEP2020)	N/N
1 1015 10151045	3^	GASTR	Nausea/ Nausea	1	08SEP2020	23/2	1	No	CD	NA	R (09SEP2020)	N/N
1 1015 10151045	3^	GASTR	Diarrhoea/ Diarrhea	1	17AUG2020	1/1	1	Yes		NA	R (17AUG2020)	N/N
1 1015 10151046	3^	GENRL	Chills/ Chills	2	12SEP2020	5/2	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1015 10151047	3^	MUSC	Pyrexia/ Fever	2	12SEP2020	5/2	1	Yes		NA	R (13SEP2020)	N/N
			Myalgia/ Muscle Aches	2	12SEP2020	5/2	1	Yes		NA	R (13SEP2020)	N/N
		EYE	Corneal irritation/ Right corneal irritation	1	17AUG2020	1/4	2	No	O	NA	R (20AUG2020)	N/N
		GENRL	Shoulder injury related to vaccine administration/ SIRVA - shoulder injury related to vaccine administration	2	09SEP2020	1/C	3	Yes		NA	RG	Y/N
16-55/ C459100 1 1015 10151049	3^	RESP	Oropharyngeal pain/ Sore throat	2	21SEP2020	13/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1015 10151051	3^	GENRL	Injection site pain/ Soreness of injection site arm	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1015 10151054	3^	GENRL	Pyrexia/ Fever 101.2	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
			Malaise/ general malaise	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ low grade fever (100.0 F)	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1015 10151055	3^	GENRL	Fatigue/ Fatigue	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		INV	Body temperature increased/ Increased temperature of 99 degrees Fahrenheit	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 1 1015 10151061	3^	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1015 10151063	3^	GENRL	Injection site pain/ Soreness at injection site	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/Y
16-55/ C459100 1 1015 10151068	3^	GENRL	Vaccination site pain/ Pain in arm at site of tetanus shot	2	28OCT2020	49/2	1	No	CD	NA	R (29OCT2020)	N/N
16-55/ C459100 1 1015 10151077	3^	GENRL	Fatigue/ Fatigue	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
			Injection site pain/ Soreness over the injection site	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
		MUSC	Arthralgia/ Shoulder pain located lateral to deltoid muscle, near acromion.	2	09SEP2020	1/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1015 10151081	3^	GENRL	Injection site pain/ Soreness at injection site	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
1 1015 10151082	3^	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
1 1015 10151083			Injection site pain/ Arm soreness at injection site	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1015 10151084	3^	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/4	1	Yes		NA/TC	R (14SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	11SEP2020	1/4	1	Yes		NA/TC	R (14SEP2020)	N/N
			Pyrexia/ Fever	2	11SEP2020	1/4	1	Yes		NA/TC	R (14SEP2020)	N/N
		NERV	Headache/ Headache	2	12SEP2020	2/3	1	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C459100 1 1015 10151089	3^	BLOOD	Lymphadenopathy/ Swollen left axillary lymph node	2	11SEP2020	1/8	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INJ&P	Procedural pain/ Whole arm pain - received injection	2	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100 1 1015 10151092	3^	GENRL	Pyrexia/ Fever T 100.3F	2	16SEP2020	3/2	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1015 10151101	3^	METAB	Gout/ Gout	2	01OCT2020	17/12	1	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C459100 1 1015 10151102	3^	GENRL	Chills/ Chills	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ Soreness at injection site	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1015 10151115	3^	GENRL	Injection site pain/ Injection site soreness	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Malaise/ General malaise	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1015 10151116	3^	GENRL	Injection site pain/ Injection site pain	2	21SEP2020	1/C	1	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1015 10151122	3^	MUSC	Pain in extremity/ Soreness in left arm	1	26AUG2020	1/4	2	Yes		NA	R (29AUG2020)	N/Y
		GENRL	Chest discomfort/ Tightness in chest	1	07SEP2020	13/3	1	No	O	NA	R (09SEP2020)	N/N
		GENRL	Injection site pain/ Soreness in injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/Y
		GASTR	Diarrhoea/ Diarrhea	2	19OCT2020	34/2	1	No	O	NA	R (20OCT2020)	N/N
			Vomiting/ Vomiting	2	19OCT2020	34/2	1	No	O	NA	R (20OCT2020)	N/N
16-55/ C459100 1 1015 10151130	3^	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1015 10151131	3^	GENRL	Vessel puncture site induration/ 3mm induration in left antecubital area at the phlebotomy site	1	28AUG2020	2/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1015 10151132	3^	GENRL	Injection site pain/ Soreness at injection site	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
			Pain/ Body aches	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
			Pyrexia/ Fever 101.2	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1015 10151134	3^	NERV	Headache/ Headache	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N	
		EAR	Vertigo/ Worsening and continuing episode of Vertigo	1	28AUG2020	2/C	2	Yes		P	RG	N/N	
		GASTR		Diarrhoea/ Diarrhea	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
				Nausea/ Nausea	1	28AUG2020	2/5	1	Yes		NA	R (01SEP2020)	N/N
	16-55/ C459100 1 1015 10151139	3^	NERV	Headache/ Headache	1	28AUG2020	2/5	1	Yes		NA	R (01SEP2020)	N/N
			RESP	Nasal congestion/ Nasal congestion	2	29SEP2020	12/C	1	No	O	NA	RG	N/N
	16-55/ C459100 1 1015 10151143	3^	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	16-55/ C459100 1 1015 10151148	3^	GASTR	Diarrhoea/ Single episode of diarrhea	1	02SEP2020	3/1	1	Yes		NA	R (02SEP2020)	N/N
GENRL			Injection site pain/ Injection site soreness	2	23SEP2020	2/C	1	Yes		NA	RG	N/N	
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1015 10151153		GENRL	Fatigue/ Fatigue	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1015 10151154	3^	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ Soreness at injection site	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	23SEP2020	2/2	2	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1015 10151157	3^	GENRL	Pain/ Body aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
			Pyrexia/ Fever - 99.2	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1015 10151161	3^	GENRL	Injection site pain/ Soreness of injection site	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
			Pyrexia/ Low grade temperature	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		NERV	Headache/ Headache	1	01SEP2020	1/3	3	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1015 10151166	3^	GENRL	Pyrexia/ Fever - 100.7	2	21SEP2020	1/1	1	Yes		NA/TC	R (21SEP2020)	N/Y
		INJ&P	Procedural pain/ Whole arm pain - received IP	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/Y
		MUSC	Myalgia/ Myalgias	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ Upper left arm pain - pain in the deltoid, bicep and tripep muscles with movement	1	02SEP2020	1/C	1	Yes		NA	RG	N/Y
		GENRL	Injection site pain/ Arm injection site sorness (Pain)	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
			Pyrexia/ Fever	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
		NERV	Headache/ Headache	1	03SEP2020	2/C	1	Yes		NA	RG	N/N
		GENRL	Chills/ Chills	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
			Injection site pain/ Injection site soreness	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
			Pyrexia/ Fever - 102.0	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100	3^	MUSC	Myalgia/ Muscle aches	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness	1	02SEP2020	1/3	3	Yes		NA/TC	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1015 10151170	3^	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/4	2	Yes		NA/TC	R (26SEP2020)	N/N
1 1015 10151171			Injection site pain/ Soreness at injection site	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
			Pyrexia/ Fever - 99.6	2	23SEP2020	1/4	2	Yes		NA/TC	R (26SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	23SEP2020	1/4	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100 1 1015 10151174	3^	GENRL	Fatigue/ Fatigue	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/Y
			Injection site pain/ Pain at injection site	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/Y
			Pyrexia/ Fever 99.5	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/Y
		GENRL	Chills/ Chills	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
			Fatigue/ Fatigue	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ Fever 102.6	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Pyrexia/ Fever 100.2	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11015 10151175	3^	GENRL	Injection site pain/ Injection site soreness in left arm	1	03SEP2020	1/C	1	Yes		NA	RG	N/N
16-55/ C459100 11015 10151176	3^	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ Soreness at injection site	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 11015 10151177	3^	GENRL	Injection site pain/ Soreness at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/Y
			Pyrexia/ Mild fever	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/Y
		GENRL	Chills/ Chills	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N
			Injection site pain/ Muscle pain at injection site	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N
			Pain/ Body aches	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N
			Pyrexia/ Fever - 100.0	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1015 10151184	3^	NERV	Headache/ Headache	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N	
		GENRL	Pain/ Body aches	1	04SEP2020	1/2	1	Yes		NA/TC	R (05SEP2020)	N/Y	
			Pyrexia/ Fever - 99.4	1	04SEP2020	1/2	1	Yes		NA/TC	R (05SEP2020)	N/Y	
			GENRL	Pyrexia/ Fever - 99.0	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
			MUSC	Myalgia/ Muscle pain	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
			NERV	Headache/ Headache	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
		3^	GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/Y
		3^	GENRL	Injection site paraesthesia/ Tingling at injection site, down arm	1	07SEP2020	1/C	1	Yes		NA	RG	N/N
			GENRL	Fatigue/ Fatigue	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ Soreness at injection site	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/N	
			Pyrexia/ Fever 99.9	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1015 10151188	3^	MUSC	Myalgia/ Generalized muscle aches	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ Fever 100.3	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1015 10151192	3^	MUSC	Myalgia/ Muscel aches	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Injection site pain/ Soreness at injection site	1	07SEP2020	1/4	1	Yes		NA	R (10SEP2020)	N/Y
16-55/ C459100 1 1015 10151199	3^	GENRL	Pyrexia/ Fever - 101.0	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 1 1015 10151203	3^	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
			Injection site pain/ Soreness of injection site	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		SKIN	Rash/ Rash - both shins	2	15OCT2020	16/6	2	No	O	NA	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		SKIN	Rash/ Rash - left knee	2	25OCT2020	26/C	2	No	O	NA/TC	N	N/N
		GENRL	Peripheral swelling/ Right lower leg swollen	2	26OCT2020	27/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1015 10151205	3^	RESP	Rhinorrhoea/ Nasal discharge	1	10SEP2020	2/8	3	No	O	NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1015 10151207	3^	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
		NERV	Headache/ Worsening headache	2	29SEP2020	1/1	1	Yes		NA/TC	R (29SEP2020)	N/Y
16-55/ C459100 1 1015 10151210	3^	GENRL	Chills/ Chills	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N
		NERV	Fatigue/ Fatigue	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N
		NERV	Headache/ Headache	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1015 10151211	3^	GENRL	Injection site pain/ Soreness at injection site	1	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
		NERV	Migraine/ Migraine	1	17SEP2020	8/3	2	No	O	NA/TC	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ Soreness at injection site	2	01OCT2020	1/C	1	Yes		NA/TC	RG	N/Y
16-55/ C459100 1 1015 10151214	3^	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		MUSC	Myalgia/ Muscle ache near chest area	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		NERV	Headache/ Headache	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1015 10151217	3^	NERV	Migraine/ Worsening Migraine	1	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N
		GENRL	Pyrexia/ Fever	1	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1015 10151221	3^	GENRL	Injection site pain/ Pain at injection site	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1015 10151222	3^	GENRL	Chills/ Chills	2	09OCT2020	3/C	2	Yes		NA	N	N/N
			Pyrexia/ Fever - 100.7	2	09OCT2020	3/C	2	Yes		NA	N	N/N
		MUSC	Pain in extremity/ Sore arm - whole arm received investigational product	2	09OCT2020	3/C	2	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1015 10151224	3^	INJ&P	Vaccination complication/ Sore arm - whole arm where IP vaccine was received	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injectin site	2	14OCT2020	1/4	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 1015 10151225	3^	NERV	Dizziness/ Dizziness	2	08OCT2020	1/5	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C459100 1 1015 10151226	3^	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C459100 1 1015 10151229	3^	GASTR	Diarrhoea/ Diarrhea	2	13OCT2020	7/1	1	No	O	NA	R (13OCT2020)	N/N
16-55/ C459100 1 1015 10151231	3^	GENRL	Swelling face/ Swollen face	2	01NOV2020	19/1	1	No	O	NA/TC	R (01NOV2020)	N/N
		SKIN	Pruritus/ Itching all over body	2	01NOV2020	19/1	1	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C459100 1 1015 10151233	3^	GENRL	Injection site pain/ Injection site pain	1	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11015 10151234	3^	INV	Body temperature increased/ Increased temperature - 99.0	1	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	14OCT2020	1/C	2	Yes		NA	N	N/N
			Pyrexia/ Increased fever from 99.0 to 100.4	2	14OCT2020	1/C	2	Yes		NA	N	N/N
		INJ&P	Administration related reaction/ Sore arm - whole arm that received IP	2	14OCT2020	1/C	2	Yes		NA	N	N/N
		NERV	Headache/ Headache	2	14OCT2020	1/C	2	Yes		NA	N	N/N
		GENRL	Asthenia/ Low energygy	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		INJ&P	Vaccination complication/ Sore arm - Whole arm where IP vaccine was received	1	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100	2^	NERV	Headache/ Headache	1	12OCT2020	6/1	1	No	O	NA	R (12OCT2020)	N/N
		GENRL	Chills/ Chills	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
			Injection site pain/ Injection site pain	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C459100	2^	MUSC	Muscle spasms/ Back Muscle Cramp	2	04SEP2020	18/3	3	No	O	NA/TC/TCN	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1016 10161009	3^	IN FEC	Urinary tract infection/ Urinary Tract Infection	2	08SEP2020	21/7	1	No	O	NA/TC	R (14SEP2020)	N/N
1 1016 10161020	3^	SKIN	Dermatitis contact/ Contact dermatitis	1	08AUG2020	6/8	2	No	O	NA/TC	R (15AUG2020)	N/N
1 1016 10161028	3^	GASTR	Salivary gland calculus/ Left Parotid Sialolithiasis	2	21SEP2020	29/2	1	No	O	NA/TC	R (22SEP2020)	N/N
1 1016 10161031	3^	IN FEC	Herpes zoster/ zoster without complications(shingles)	2	06SEP2020	13/C	1	No	O	NA/TC	N	N/N
1 1016 10161054		SKIN	Dermatitis contact/ contact dermatitis, right thigh and right side of neck	2	06SEP2020	13/C	1	No	O	NA/TC	N	N/N
1 1016 10161057	3^	VASC	Lymphoedema/ lymphedema	2	19SEP2020	24/5	2	No	O	NA/TC	R (23SEP2020)	N/N
1 1016 10161080	3^	MUSC	Neck pain/ cervicalgia	2	21SEP2020	26/3	1	No	O	NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1016 10161087	3 [^]	GENRL	Injection site swelling/ injection site swelling	1	10AUG2020	1/10	3	Yes		P/TC	R (19AUG2020)	N/N
16-55/ C459100 1 1016 10161093	3 [^]	EYE	Vision blurred/ Blurry vision in Left Eye	2	08SEP2020	8/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1016 10161107	3 [^]	GASTR	Nausea/ Nausea	2	04SEP2020	4/2	1	Yes		NA	R (05SEP2020)	N/N
		RESP	Oropharyngeal pain/ Sore Throat	2	04SEP2020	4/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1016 10161126	3 [^]	MUSC	Back pain/ Low Back Pain	1	17AUG2020	4/4	2	No	O	NA/TC	R (20AUG2020)	N/N
16-55/ C459100 1 1016 10161154	3 [^]	GENRL	Pyrexia/ fever	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1016 10161181	3 [^]	GENRL	Injection site pain/ Injection Site Pain	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
		MUSC	Arthralgia/ Joint Pain, Generalized	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
			Myalgia/ Generalized Muscle Pain	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1016 10161186	3^	GENRL	Injection site pain/ injection site pain	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1016 10161192	3^	INFEC	Sinusitis/ sinusitis	2	08OCT2020	23/4	1	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C459100 1 1016 10161193	3^	GENRL	Chills/ chills	2	15SEP2020	1/1	2	Yes		NA	R (15SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	15SEP2020	1/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1016 10161210	3^	GASTR	Vomiting/ vomiting	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Chills/ chills	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ fever	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1016 10161216	3^	INJ&P	Radius fracture/ Left Radial Head Fracture	1	04SEP2020	4/C	2	No	O	NA/TCN	N	N/N
16-55/ C459100 1 1016 10161218	3^	GENRL	Chills/ chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1016 10161226	3^	MUSC	Fatigue/ fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Myalgia/ muscle pain, unknown	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GASTR	Nausea/ nausea	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Chills/ chills	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1016 10161230	3^	GENRL	Pyrexia/ fever	2	23SEP2020	1/3	1	Yes		NA/TC	R (25SEP2020)	N/N
			Chills/ chills	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		MUSC	Pyrexia/ fever	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1016 10161231	3^	GENRL	Myalgia/ muscle pain	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
			Vessel puncture site haematoma/ hematoma at blood draw site	2	21OCT2020	29/C	1	No	O	NA	N	N/N
		RESP	Nasal congestion/ nasal congestion	1	11SEP2020	10/4	1	No	O	NA/TC	R (14SEP2020)	N/N
		SKIN	Rash/ diffuse rash(everywhere but more on neck,chest,back)	1	11SEP2020	10/4	1	No	O	NA/TC	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1016 10161245	3^	PSYCH	Depression/ worsening depression	1	10SEP2020	7/C	1	No	O	NA/TC	N	N/N
		GENRL	Injection site pain/ injection site pain	2	24SEP2020	1/4	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1016 10161248	3^	GENRL	Pyrexia/ fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1016 10161268	3^	INJ&P	Skin laceration/ laceration to nose	2	25OCT2020	27/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1016 10161276	3^	SKIN	Dermatitis contact/ contact dermatitis on bilateral lower legs	2	26OCT2020	28/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1016 10161277	3^	CARD	Atrial fibrillation/ atrial fibrillation	2	09OCT2020	8/4	2	No	O	NA/TC	R (12OCT2020)	Y/N
16-55/ C459100 1 1016 10161289	3^	GENRL	Chills/ chills	1	18SEP2020	1/3	2	Yes		NA/TC	R (20SEP2020)	N/N
			Pyrexia/ fever	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
		INJ&P	Concussion/ concussion	2	31OCT2020	25/C	2	No	O	NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Relative ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Facial bones fracture/ facial fractures	2	31OCT2020	25/C	3	No	O	NA/TC	RG	Y/N
			Road traffic accident/ motor vehicle accident	2	31OCT2020	25/1	3	No	O	NA	R (31OCT2020)	N/N
16-55/ C459100 1 1016 10161300	3^	GENRL	Pyrexia/ Fever	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1018 10181028	3^	NERV	Cervical radiculopathy/ cervical radiculopathy C5-C6	1	12AUG2020	10/14	2	No	O	NA/TC/TCN	R (25AUG2020)	N/N
16-55/ C459100 1 1018 10181039	3^	INFEC	Upper respiratory tract infection/ Upper respiratory infection	1	18AUG2020	16/20	1	No	O	NA/TC	R (06SEP2020)	N/N
16-55/ C459100 1 1018 10181049	3^	INJ&P	Ligament sprain/ Right Ankle Sprain	1	15AUG2020	12/2	1	No	O	NA/TC	R (16AUG2020)	N/N
16-55/ C459100 1 1018 10181050	3^	GASTR	Food poisoning/ Food Poisoning	1	01SEP2020	29/3	1	No	O	NA	R (03SEP2020)	N/N
16-55/ C459100 1 1018 10181062	3^	EYE	Dry eye/ Right Eye Dryness	1	08AUG2020	4/15	1	No	O	NA	R (22AUG2020)	N/N
		INJ&P	Contusion/ Right third finger contusion	1	21AUG2020	17/8	2	No	O	NA/TCN	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Arthralgia/ right ankle pain	1	23AUG2020	19/8	2	No	O	NA	R (30AUG2020)	N/N
		NERV	Presyncope/ Vasovagal Reaction (to Blood draw)	2	25SEP2020	31/1	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C459100 1 1018 10181064	3^	INFEC	Hordeolum/ Hordeolum	2	12SEP2020	15/7	2	No	O	NA/TC/TCN	R (18SEP2020)	N/N
16-55/ C459100 1 1018 10181081	3^	INFEC	Paronychia/ Left Hallux Ingrown Toenail (Infected)	1	14AUG2020	10/C	2	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 1 1018 10181084	3^	GENRL	Fatigue/ Fatigue	2	26AUG2020	1/9	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Chest pain/ Sharp Pain, Mid-Sternal	2	27AUG2020	2/1	1	No	O	NA	R (27AUG2020)	N/N
16-55/ C459100 1 1018 10181089	3^	GENRL	Pain/ Body aches/pains, Full body	2	28AUG2020	2/1	3	Yes		NA/TC	R (28AUG2020)	N/N
		NERV	Headache/ headache	2	28AUG2020	2/1	3	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 1 1018 10181118	3^	GENRL	Medical device pain/ Pain in mouth due to dental implant	1	31AUG2020	22/3	1	No	O	NA/TC	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1018 10181120	3^	GASTR	Abdominal pain/ Abdominal Pain	1	24AUG2020	15/7	1	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C459100 1 1018 10181133	3^	SURG	Wisdom teeth removal/ Wisdom tooth extraction	1	20AUG2020	9/1	1	No	O	NA/TC	R (20AUG2020)	N/N
16-55/ C459100 1 1018 10181144	3^	NERV	Headache/ Headache	2	11SEP2020	2/14	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1018 10181145	3^	NERV	Headache/ Headache	2	14SEP2020	12/1	1	No	O	NA	R (14SEP2020)	N/N
		SKIN	Dermatitis allergic/ Allergic reaction (entire body), rash	2	14SEP2020	12/2	2	No	O	NA	R (15SEP2020)	N/N
16-55/ C459100 1 1018 10181159	3^	UNC	LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@/ Lower back pain and bilateral lower extremity pain with radicular paresthesia	2	20OCT2020	47/C	2	Yes		NA/TC	RG	Y/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1018 10181174	3^	GENRL	Injection site pain/ Injection Site Pain, Left deltoid	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
1 1018 10181182	3^	INJ&P	Ligament sprain/ Back Sprain/Strain	2	01OCT2020	22/C	2	No	O	NA/TC	RG	N/N
1 1018 10181184	3^	GENRL	Injection site pain/ Pain at the injection side - Left Shoulder	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
		INV	Body temperature increased/ Elevation of Body temperature 98.7 F	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
		MUSC	Arthralgia/ Generalized Joints Pain	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1018 10181186	3^	GASTR	Faeces soft/ Soft Stools	2	02SEP2020	1/6	1	Yes		NA	R (07SEP2020)	N/N
			Nausea/ Nausea	2	02SEP2020	1/6	1	Yes		NA	R (07SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	02SEP2020	1/8	1	Yes		NA	R (09SEP2020)	N/N
		NERV	Headache/ Headache	2	02SEP2020	1/1	1	Yes		NA/TC	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Nasal congestion/ Nasal Congestion	2	28SEP2020	27/18	2	No	O	NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1018 10181188	3^	GENRL	Injection site pain/ Injection site tenderness	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C459100 1 1018 10181195	3^	GENRL	Injection site pain/ Injection site pain	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
			Injection site swelling/ Swelling at injection site	1	21AUG2020	1/1	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C459100 1 1018 10181199	3^	GENRL	Injection site swelling/ Injection Site swelling	1	11SEP2020	22/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1018 10181200	3^	GENRL	Injection site erythema/ Injection Site Redness	1	21AUG2020	1/2	2	Yes		NA	R (22AUG2020)	N/N
			Injection site pain/ Injection Site Pain	1	21AUG2020	1/2	2	Yes		NA	R (22AUG2020)	N/N
			Injection site swelling/ Injection Site Swelling	1	21AUG2020	1/2	2	Yes		NA	R (22AUG2020)	N/N
		GENRL	Chills/ Chills	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
			Pain/ Body Aches	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1018 10181201	3^	GENRL	Pyrexia/ Fever - 102.1	2	11SEP2020	2/2	3	Yes		NA/TC	R (12SEP2020)	N/N	
			NERV	Headache/ Headache	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
			Injection site pain/ Injection Site Pain	1	21AUG2020	1/2	1	Yes		NA		R (22AUG2020)	N/N
			NERV	Headache/ Headache	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
			GENRL	Chills/ Chills	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C459100 1 1018 10181206	3^	GASTR	Pyrexia/ Fever	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N	
			Nausea/ Nausea	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N	
			GENRL	Chills/ Chills	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
			NERV	Headache/ Headache	2	13SEP2020	2/2	1	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C459100 1 1018 10181207	3^	GENRL	Injection site pain/ Injection site soreness	1	23AUG2020	2/7	1	Yes		NA/TC	R (29AUG2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1018 10181208	3^	INJ&P	Post procedural discomfort/ Nasal swab site discomfort right nostril	1	23AUG2020	2/12	1	No	O	NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	11SEP2020	1/3	2	Yes		NA	R (13SEP2020)	N/N
			Injection site pain/ Soreness at the injection site	2	11SEP2020	1/5	1	Yes		NA/TC	R (15SEP2020)	N/N
		GENRL	Pyrexia/ Fever - 100.5 F	2	12SEP2020	2/1	1	Yes		NA/TC	RS (12SEP2020)	N/N
		GENRL	Pyrexia/ Fever 101.0	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	13SEP2020	3/C	1	Yes		NA	RG	N/N
		NERV	Headache/ Headache	2	13SEP2020	3/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1018 10181215	3^	GENRL	Injection site pain/ Soreness at the injection side	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
			Pain/ Body aches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
			Pyrexia/ Fever 100.9	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1018 10181221	3^	SKIN	Pruritus allergic/ Pruritus, extremities (Food or Cosmetics)	2	26SEP2020	2/4	1	No	O	NA	R (29SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1018 10181222	3^	SKIN	Urticaria/ Urticaria, extremities	2	27SEP2020	3/2	2	No	O	NA	R (28SEP2020)	N/N
		NERV	Headache/ Headache	1	29AUG2020	1/1	1	Yes		NA/TC	R (29AUG2020)	N/Y
16-55/ C459100 1 1018 10181224	3^	GENRL	Injection site pain/ Mild injection site pain	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	30AUG2020	2/4	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 1 1018 10181226	3^	GENRL	Fatigue/ Fatigue	2	19SEP2020	2/5	2	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ Low-Grade Fever	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ Muscle Pain	2	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	30AUG2020	2/4	2	Yes		NA	R (02SEP2020)	N/N
			Pyrexia/ Fever	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N
		MUSC	Pain in extremity/ Arm pain, left side	1	30AUG2020	2/6	2	Yes		NA/TC	R (04SEP2020)	N/N
		NERV	Headache/ Headache	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1018 10181228	3^	GENRL	Pyrexia/ Fever	2	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ Headache	1	20SEP2020	21/3	1	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
			Injection site pain/ Soreness at the injection site	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1018 10181230	3^	NERV	Headache/ Headache	1	06SEP2020	7/2	2	Yes		NA/TC	R (07SEP2020)	N/N
16-55/ C459100 1 1018 10181234	3^	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		MUSC	Arthralgia/ Joint Aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		VASC	Hypertension/ Worsening Hypertension	2	07OCT2020	14/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1018 10181238	3^	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Injection site pain/ Pain, injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ Chills	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		NERV	Headache/ Headache	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ Headache	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		SKIN	Urticaria/ Urticaria, Bilateral Arms progressing to lower extremities	2	25SEP2020	2/C	2	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1018 10181244	3^	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1018 10181246	3^	GENRL	Pyrexia/ Fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
		INV	Blood pressure increased/ Elevated Blood Pressure	2	27OCT2020	33/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1018 10181247	3^	METAB	Hyperlipidaemia/ Hyperlipidemia	2	20OCT2020	26/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INV	Blood pressure increased/ Elevated Blood Pressure without Dx of Hypertension	2	27OCT2020	33/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1018 10181256	3^	NERV	Headache/ Headache	1	02SEP2020	1/6	1	Yes		NA	R (07SEP2020)	N/N
		GENRL	Injection site pain/ Injection Pain	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ Chill	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
			Injection site pain/ Injection Pain	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1018 10181261	3^	GENRL	Pyrexia/ Fever, low grade	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Migraine/ migraine	2	08OCT2020	16/2	1	No	CD	NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1018 10181267	3^	VASC	Hypertension/ Worsening of hypertension	2	12OCT2020	18/8	1	No	O	NA/TC	R (19OCT2020)	N/N
16-55/ C459100	3^	GENRL	Pain/ Body aches	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1018 10181279			Pyrexia/ Fever, low grade	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1018 10181283	3^	GENRL	Injection site pain/ Soreness at the Left Shoulder - Injection site	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C459100 1 1018 10181284	3^	GENRL	Fatigue/ fatigue	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1018 10181287	3^	GENRL	Injection site pain/ Soreness at injection site	1	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at injection site	2	05OCT2020	1/5	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1018 10181288	3^	GASTR	Diarrhoea/ diarrhea	1	15SEP2020	2/1	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C459100 1 1018 10181294	3^	GASTR	Palatal disorder/ Palate irritation	1	17SEP2020	3/5	1	No	O	NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Paranasal sinus discomfort/ Sinus pressure	1	17SEP2020	3/1	1	No	O	NA	R (17SEP2020)	N/N
16-55/ C459100 1 1018 10181295	3^	REPRO	Erectile dysfunction/ erectile dysfunction	1	18SEP2020	3/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1018 10181305	3^	GASTR	Diarrhoea/ Loose Stool	1	27SEP2020	7/1	1	No	O	NA	R (27SEP2020)	N/N
16-55/ C459100 1 1019 10191047	3^	GENRL	Injection site pain/ Injection Pain Moderate	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
		GENRL	Injection site pain/ Injection Pain Mild	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 1 1019 10191063	3^	NERV	Head discomfort/ Head Pressure	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1019 10191140	3^	RESP	Asthma/ Worsening of Asthma	2	12OCT2020	22/6	1	No	O	NA	R (17OCT2020)	N/N
16-55/ C459100 1 1019 10191159	3^	GENRL	Chills/ Chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
			Fatigue/ Fatigue	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1019 10191175	3^	GENRL	Pain/ Moderate Body Aches	1	10SEP2020	2/6	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1019 10191206	3^	GENRL	Pain/ Body Aches	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1019 10191215	3^	BLOOD	Lymphadenopathy/ Axial Lymph Node Swelling Left	1	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
		GENRL	Injection site pain/ Left arm site injection pain	1	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
		GENRL	Chills/ chills	2	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
			Fatigue/ Fatigue	2	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
			Injection site pain/ L Arm Pain Injection Site	2	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1019 10191242	3^	GENRL	Injection site pain/ Injection Site Pain	1	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1019 10191249	3^	GASTR	Nausea/ Nausea	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1019 10191254	3^	GENRL	Fatigue/ Fatigue	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
			Pain/ Body Aches	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
		INFEC	Urinary tract infection/ Urinary Tract Infection	1	15OCT2020	11/10	3	No	O	NA	R (24OCT2020)	Y/N
		NEOPL	Benign pancreatic neoplasm/ Serous cystadenoma of Pancreas	1	24OCT2020	20/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1021 10211032	3^	GENRL	Chills/ Body chills	1	20AUG2020	8/1	1	No	O	NA	R (20AUG2020)	N/N
16-55/ C459100 1 1021 10211083	3^	GASTR	Nausea/ Nausea	2	28SEP2020	15/2	1	No	O	NA	R (29SEP2020)	N/N
16-55/ C459100 1 1021 10211104	3^	GASTR	Diarrhoea/ Diarrhea	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
			Nausea/ Nausea	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
			Vomiting/ Vomiting	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at Injection Site	2	18SEP2020	2/3	2	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1021 10211117	3^	GENRL	Fatigue/ Fatigue	1	29AUG2020	2/3	2	Yes		NA	R (31AUG2020)	N/N
			Pyrexia/ Fever	1	29AUG2020	2/3	2	Yes		NA	R (31AUG2020)	N/N
		GENRL	Pyrexia/ Fever	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
		RESP	Asthma/ Worsening of Asthma	2	19SEP2020	2/C	2	Yes		NA	N	N/N
16-55/ C459100 1 1021 10211156	3^	INFEC	Conjunctivitis/ R Eye Conjunctivits	1	22SEP2020	19/6	2	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C459100 1 1021 10211185	3^	RESP	Asthma/ Worsening of Asthma	2	12OCT2020	14/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1021 10211212	3^	INJ&P	Tooth fracture/ Ruptured Tooth	1	27SEP2020	13/2	2	No	O	NA/TC/TCN	R (28SEP2020)	N/N
16-55/ C459100 1 1021 10211223	3^	GENRL	Injection site pain/ muscle soreness at injection site	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ fever	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1021 10211235	3^	GENRL	Fatigue/ fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1021 10211240	3^	GENRL	Chills/ Chills	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N
			Fatigue/ Fatigue	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C459100 1 1021 10211244	3^	GENRL	Injection site pain/ Left Arm Soreness at Injection Site	2	12OCT2020	1/4	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1022 10221017	3^	GENRL	Injection site pain/ Pain at the injection site	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ Fever	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
		MUSC	Myalgia/ Generalized Myalgias	2	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1022 10221018	3^	GENRL	Injection site pain/ Mild Injection Site Pain	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ Moderate Fatigue	2	09SEP2020	2/4	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1022 10221020	3^	INFE	Urinary tract infection/ Urinary Tract Infection	2	07OCT2020	27/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1022 10221023	3^	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
			Pain/ Body Aches	2	09SEP2020	1/1	2	Yes		NA	R (09SEP2020)	N/N
		MUSC	Myalgia/ Generalized Myalgias	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Headache	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1022 10221024	3^	GENRL	Axillary pain/ Axillary Pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
		MUSC	Groin pain/ Groin Pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
		GASTR	Diarrhoea/ Loose Stools	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		BLOOD	Lymphadenopathy/ Lymphadenopathy of Head (left side)	2	22SEP2020	15/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1022 10221025	3^	GENRL	Injection site pain/ Injection Site Pain	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
		NERV	Headache/ Headache	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
		GASTR	Nausea/ Nausea	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
		GENRL	Pain/ Body Aches	2	09SEP2020	2/2	2	Yes		NA/TC	R (10SEP2020)	N/N
		NERV	Headache/ Headache	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1022 10221027	3^	GENRL	Injection site pain/ Injection Site Pain	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		MUSC	Arthralgia/ Medial Pain left knee	2	20SEP2020	10/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1022 10221033	3^	GENRL	Injection site pain/ Mild Injection Site Pain	1	20AUG2020	1/1	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C459100 1 1022 10221035	3^	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1022 10221040	3^	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1022 10221049	3^	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1022 10221051	3^	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/2	2	Yes		NA	R (25AUG2020)	N/N
16-55/ C459100 1 1022 10221052	3^	GASTR	Nausea/ Nausea	1	24AUG2020	1/1	2	Yes		NA	R (24AUG2020)	N/N
16-55/ C459100 1 1022 10221054	3^	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
			Injection site pain/ Pain at the injection site	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1022 10221055	3^	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1022 10221064	3 [^]	GENRL	Fatigue/ Fatigue	2	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ Injection site pain	2	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ Generalized Myalgias	2	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
		RESP	Oropharyngeal pain/ Sore Throat	2	21SEP2020	6/4	1	No	O	NA	R (24SEP2020)	N/N
			Paranasal sinus discomfort/ Sinus Pressure	2	21SEP2020	6/4	1	No	O	NA	R (24SEP2020)	N/N
			Upper-airway cough syndrome/ Post Nasal Drainage	2	21SEP2020	6/4	1	No	O	NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	1/3	2	Yes		NA	R (27AUG2020)	N/N
		GASTR	Nausea/ Nausea	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		GENRL	Chills/ Moderate Chills	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ Generalized myalgias	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1022 10221070	3 [^]	NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1022 10221074	3^	GENRL	Injection site pain/ Mild Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
			Chills/ Chills	2	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
		NERV	Fatigue/ Moderate fatigue	2	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ Moderate pain at the injection site	2	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ Fever	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
			Headache/ Mild Headache	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1022 10221076	3^	GENRL	Injection site pain/ Injection Site Pain	1	27AUG2020	1/1	1	Yes		NA	R (27AUG2020)	N/N
		NERV	Headache/ Headache	1	27AUG2020	1/1	1	Yes		NA/TC	R (27AUG2020)	N/N
16-55/ C459100 1 1022 10221080	3^	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
			Malaise/ Malaise	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		PSYCH	Abnormal dreams/ Unusually Vivid Dreams	1	27AUG2020	1/2	2	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1022 10221081	3^	GENRL	Injection site bruising/ Bruise at the injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 1 1022 10221084	3^	MUSC	Back pain/ Musculoskeletal Pain upper back	1	14SEP2020	19/5	2	No	O	NA	R (18SEP2020)	N/N
16-55/ C459100 1 1022 10221087	3^	NERV	Headache/ Headache*		28AUG2020	1/1	2	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 1 1022 10221093	3^	GENRL	Injection site pain/ Moderate Injection site pain	1	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
16-55/ C459100 1 1022 10221100	3^	GENRL	Injection site pain/ Moderate Injection site pain	1	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/Y
16-55/ C459100 1 1022 10221106	3^	GASTR	Nausea/ Nausea	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
			Vomiting/ Vomiting	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ Chills	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
			Injection site pain/ Moderate Injection site pain	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1022 10221108	3^	SKIN	Hyperhidrosis/ Sweats	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ Chills	2	22SEP2020	2/C	2	Yes		NA	N	N/N
			Injection site pain/ Moderate Injection site pain	2	22SEP2020	2/C	2	Yes		NA	N	N/N
			Pyrexia/ Fever	2	22SEP2020	2/C	1	Yes		NA	N	N/N
		MUSC	Myalgia/ Moderate Generalized Myalgias	2	22SEP2020	2/C	2	Yes		NA	N	N/N
		GENRL	Injection site pain/ Mild Injection site pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/Y
		MUSC	Myalgia/ Moderate Myalgias	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ Moderate Headache	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1022 10221110	3^	GENRL	Chills/ Moderate Chills	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		BLOOD	Lymphadenopathy/ Left Axillary Adenopathy	2	24SEP2020	3/5	1	Yes		NA	R (28SEP2020)	N/N
		GENRL	Injection site pain/ Achy pain around injection site	1	11SEP2020	10/C	1	Yes		NA	N	N/N
		GASTR	Nausea/ Mild Nausea	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1022 10221112	3^	GENRL	Chills/ Chills	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/Y
		GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y
16-55/ C459100 1 1022 10221120	3^	NERV	Headache/ Headache	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	1/4	2	Yes		NA	R (27SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/7	2	Yes		NA	R (09SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ Generalized Myalgias	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1022 10221122	3^	GENRL	Injection site pain/ Mild Injection site pain	1	03SEP2020	1/5	1	Yes		NA	R (07SEP2020)	N/N
		GASTR	Nausea/ Moderate Nausea	1	04SEP2020	2/1	2	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Mild Injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1022 10221123		MUSC	Myalgia/ Moderate Myalgias	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1022 10221125	3^	GENRL	Chills/ Moderate Chills	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
			Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1022 10221128	3^	GENRL	Oedema peripheral/ Bilateral Hand Edema	1	05SEP2020	2/1	1	No	O	NA	R (05SEP2020)	N/N
		RESP	Rhinorrhoea/ Rhinorrhea	1	05SEP2020	2/1	1	No	O	NA	R (05SEP2020)	N/N
		REPRO	Breast cyst/ Right Breast Cyst	2	20OCT2020	27/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1022 10221133	3^	MUSC	Myalgia/ Generalized Moderate Myalgias*		04SEP2020	1/2	2	Yes		NA	R (05SEP2020)	N/N
		NERV	Headache/ Moderate Headache*		04SEP2020	1/2	2	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ Mild Chills	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1022 10221136	3^	MUSC	Myalgia/ Generalized Myalgias	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ Mild Headache	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
		GENRL	Injection site pain/ Moderate Injection site pain	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 1 1022 10221138	3^	NERV	Headache/ Mild Headache	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 1 1022 10221139	3^	NERV	Headache/ Mild Headache	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Injection site pain/ Mild Injection Site Pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		GASTR	Diarrhoea/ Episodes of loose stools	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Mild Injection Site Pain	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
		NERV	Headache/ Headache	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
		INJ&P	Arthropod bite/ Mosquito Bite inner thigh	2	10OCT2020	13/7	1	No	O	NA/TC	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1022 10221142	3^	GENRL	Injection site pain/ Injection Site pain	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
1 1022 10221144		GENRL	Chills/ Mild Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ Mild injection site pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Myalgia/ Mild generalized myalgias	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100	3^	SKIN	Mechanical urticaria/ Worsening of Dermographism of TRUNK	1	13SEP2020	5/43	1	No	O	NA	R (25OCT2020)	N/N
1 1022 10221147	3^	GENRL	Chills/ Chills	2	05OCT2020	1/1	2	Yes		NA	R (05OCT2020)	N/N
16-55/ C459100		MUSC	Myalgia/ Generalized Myalgias	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
1 1022 10221156		NERV	Headache/ Headache	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Mild Injection Site Pain	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
1 1022 10221164												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Flank pain/ Moderate left flank pain	1	02OCT2020	16/C	2	No	O	NA/TC/TCN	N	N/N
		GENRL	Injection site pain/ Mild Injection Site Pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
			Injection site papule/ Erythematous Papules around injection site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		EAR	Vertigo positional/ Benign Paroxysmal Positional Vertigo	2	16OCT2020	9/C	2	No	O	NA	N	N/N
16-55/ C459100 1 1024 10241004	3^	GASTR	Diarrhoea/ Diarrhea	1	14AUG2020	3/1	1	No	O	NA	R (14AUG2020)	N/N
16-55/ C459100 1 1024 10241061	3^	GENRL	Pain/ Body Aches	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1024 10241104	3^	MUSC	Arthralgia/ Joint Pain - Elbows	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
			Arthralgia/ Joint pain - Knees	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
			Arthralgia/ Joint pain - Neck	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ chills	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1024 10241114		GENRL	Pain/ generalized body aches	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 1 1027 10271061	3^	GENRL	Fatigue/ FATIGUE	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
			Pain/ BODY ACHES	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
16-55/ C459100 1 1027 10271105	3^	IMMUN	Allergy to vaccine/ Allergic Reaction to Study Vaccine	1	29AUG2020	2/14	2	Yes		P/TC	R (11SEP2020)	N/N
		RESP	Pharyngeal swelling/ Throat Swelling	1	29AUG2020	2/11	2	Yes		NA/TC	R (08SEP2020)	N/N
		GASTR	Gastroesophageal reflux disease/ GERD	1	08SEP2020	12/C	1	No	O	NA/TC	RG	N/N
		GENRL	Chest pain/ Left-sided chest pain	1	08SEP2020	12/1	1	No	O	NA/TC	R (08SEP2020)	N/N
		MUSC	Back pain/ Lower back pain	1	08SEP2020	12/4	1	No	O	NA	R (11SEP2020)	N/N
		MUSC	Muscular weakness/ Right leg weakness	1	10SEP2020	14/1	2	No	O	NA/TCN	R (10SEP2020)	N/N
		MUSC	Back pain/ Mid back pain	1	11SEP2020	15/4	1	No	O	NA	R (14SEP2020)	N/N
		NERV	Hypoesthesia/ Right arm numbness	1	11SEP2020	15/1	1	No	O	NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1027 10271129	3^	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactivity Disorder	2	19OCT2020	27/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1028 10281022	3^	GENRL	Injection site pain/ Left Arm Pain at injection site	1	19AUG2020	1/2	2	Yes		NA	R (20AUG2020)	N/N
		GENRL	Fatigue/ fatigue	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
			Pain/ body aches	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		MUSC	Pain in extremity/ left arm soreness	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1028 10281023	3^	BLOOD	Leukocytosis/ leukocytosis	2	05OCT2020	19/1	2	No	O	NA	R (05OCT2020)	N/N
		GASTR	Abdominal pain/ abdominal pain	2	05OCT2020	19/1	2	No	O	NA/TC	R (05OCT2020)	N/N
			Nausea/ nausea	2	05OCT2020	19/2	2	No	O	NA/TC	R (06OCT2020)	N/N
			Vomiting/ vomiting	2	05OCT2020	19/1	2	No	O	NA	R (05OCT2020)	N/N
		METAB	Dehydration/ dehydration	2	05OCT2020	19/1	2	No	O	NA/TC	R (05OCT2020)	N/N
		RENAL	Acute kidney injury/ acute kidney injury	2	05OCT2020	19/1	2	No	O	NA	R (05OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1028 10281026	3^	MUSC	Pain in extremity/ bilateral hand pain	2	14SEP2020	4/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C459100 1 1028 10281027	3^	GENRL	Chills/ CHILLS	2	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N
			Pain/ BODY ACHES	2	12SEP2020	2/2	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100 1 1028 10281030	3^	NERV	Dystonia/ Dystonia	1	23AUG2020	4/1	2	No	CD	NA/TC	R (23AUG2020)	N/N
16-55/ C459100 1 1028 10281031	3^	GASTR	Cheilitis/ RASH RIGHT UPPER LIP	1	01SEP2020	13/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1028 10281033	3^	INV	Body temperature increased/ elevated body temperature	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N
16-55/ C459100 1 1028 10281035	3^	GENRL	Injection site erythema/ left arm redness at injection site	1	21AUG2020	1/3	2	Yes		NA	R (23AUG2020)	N/N
			Injection site pain/ left arm soreness at injection site	1	21AUG2020	1/3	2	Yes		NA	R (23AUG2020)	N/N
			Injection site swelling/ left arm swelling at injection site	1	21AUG2020	1/3	2	Yes		NA	R (23AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1028 10281043	3^	GENRL	Injection site pain/ left arm soreness at injection site	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
			Injection site swelling/ left arm swelling at injection site	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
		GASTR	Haemorrhoids/ internal hemorrhoids	2	28SEP2020	15/C	2	No	O	NA	N	N/N
16-55/ C459100 1 1028 10281050	3^	INV	Body temperature increased/ increased body temperature	1	27AUG2020	4/1	2	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 1 1028 10281059	3^	INFEC	Viral upper respiratory tract infection/ Non-COVID viral Upper respiratory infection	2	05OCT2020	20/6	2	No	O	NA	R (10OCT2020)	N/N
		RESP	Asthma/ mild asthma exacerbation	2	05OCT2020	20/6	2	No	O	NA/TC	R (10OCT2020)	N/N
			Rhinitis allergic/ allergic rhinitis	2	05OCT2020	20/6	2	No	O	NA	R (10OCT2020)	N/N
		GENRL	Injection site pain/ left arm soreness at injection site.	1	27AUG2020	2/3	2	Yes		NA	R (29AUG2020)	N/N
		REPRO	Breast mass/ left breast lump	1	27AUG2020	2/34	2	No	O	NA	R (29SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	1	01SEP2020	7/1	2	Yes		NA	R (01SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NEOPL	Invasive ductal breast carcinoma/ invasive ductal carcinoma stage 1B, left breast	2	30SEP2020	15/C	2	No	O	NA	N	Y/N
16-55/ C459100 1 1028 10281060	3^	GENRL	Fatigue/ Fatigue	1	27AUG2020	2/8	2	Yes		NA	R (03SEP2020)	N/N
		INJ&P	Upper limb fracture/ Closed fracture of right elbow	2	28OCT2020	42/2	2	No	O	NA/TC/TCN	R (29OCT2020)	Y/N
16-55/ C459100 1 1028 10281062	3^	NERV	Migraine/ worsening of migraines	1	15SEP2020	21/23	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1028 10281065	3^	MUSC	Pain in extremity/ SORE ARM, LEFT	1	27AUG2020	1/2	2	Yes		NA	R (28AUG2020)	N/Y
		GENRL	Injection site erythema/ left arm redness at injection site	2	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ left arm pain at injection site	2	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ headache	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1028 10281075	3^	GENRL	Injection site erythema/ LEFT ARM INJECTION SITE REDNESS	1	28AUG2020	1/7	2	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	28AUG2020	1/7	2	Yes		NA	R (03SEP2020)	N/N
			Injection site pruritus/ LEFT ARM INJECTION SITE ICHINESS	1	28AUG2020	1/7	2	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ injection site soreness left	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ headache	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
		GASTR	Vomiting/ vomiting	2	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ chills	2	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
			Chills/ rigors	2	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1028 10281077	3^	GENRL	Injection site pain/ LEFT ARM SORENESS AT INJECTION SITE	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 1 1028 10281078	3^	GASTR	Nausea/ NAUSEA	1	29AUG2020	2/1	2	Yes		NA	R (29AUG2020)	N/N
		GENRL	Pain/ body aches	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1028 10281085	3^	INV	Body temperature increased/ increased body temperature	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ increase in headaches	1	02SEP2020	3/48	2	Yes		NA	R (19OCT2020)	N/N
16-55/ C459100 1 1028 10281087	3^	INFEC	Ear infection/ bilateral ear infection	1	05SEP2020	6/12	2	No	O	NA/TC	R (16SEP2020)	N/N
		GENRL	Injection site erythema/ redness at injection site left arm	2	22SEP2020	2/7	2	Yes		NA	R (28SEP2020)	N/N
16-55/ C459100 1 1028 10281088	3^	GASTR	Injection site pain/ pain at injection site left arm	2	22SEP2020	2/7	2	Yes		NA	R (28SEP2020)	N/N
			Injection site swelling/ swelling at injection site left arm	2	22SEP2020	2/7	2	Yes		NA	R (28SEP2020)	N/N
		Nausea/ nausea	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N	
		GENRL	Chills/ chills	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ headache	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
RESP	Oropharyngeal pain/ sore throat	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1028 10281089	3^	GENRL	Pain/ body aches	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ fever	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1028 10281090	3^	GENRL	Chills/ body chills	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ headache	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1028 10281096	3^	GENRL	Injection site pain/ injection site pain, left	1	01SEP2020	1/3	2	Yes		NA	R (03SEP2020)	N/N
		GENRL	Chills/ body chills	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
			Fatigue/ fatigue	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1028 10281098	3^	GENRL	Chills/ chills	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1028 10281103	3^	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	03SEP2020	2/7	2	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Injection site pruritus/ ITCHINESS AT INJECTION SITE	1	03SEP2020	2/7	2	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 1 1028 10281104	3^	GENRL	Fatigue/ fatigue	1	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
		INV	Body temperature increased/ increased body temperature	1	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1028 10281105	3^	MUSC	Myalgia/ right deltoid muscle pain	1	04SEP2020	3/3	2	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 1 1028 10281112	3^	MUSC	Pain in extremity/ Left Arm Soreness	1	04SEP2020	2/1	2	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1028 10281121	3^	MUSC	Myalgia/ muscle aches	1	05SEP2020	2/2	2	Yes		NA	R (06SEP2020)	N/N
		NERV	Headache/ headache	1	05SEP2020	2/2	2	Yes		NA	R (06SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ headache	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ left arm soreness at injection site	1	04SEP2020	1/3	2	Yes		NA	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1028 10281124												
16-55/ C459100	3^	NERV	Headache/ headache	1	06SEP2020	2/2	2	Yes		NA	R (07SEP2020)	N/N
1 1028 10281131												
		GENRL	Chills/ Chills	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
			Pyrexia/ Fever	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ Headache	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ fatigue	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
1 1028 10281141												
			Pain/ body aches	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ chills	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
1 1028 10281143												
		INV	Body temperature increased/ increased body temperature	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1028 10281155	3^	GENRL	Chills/ chills	2	30SEP2020	2/18	2	Yes		NA	R (17OCT2020)	N/N
			Injection site pain/ left arm injection site soreness	2	30SEP2020	2/15	2	Yes		NA	R (14OCT2020)	N/N
			Pyrexia/ fever	2	30SEP2020	2/18	2	Yes		NA/TC	R (17OCT2020)	N/N
			NERV Headache/ headache	2	30SEP2020	2/18	2	Yes		NA	R (17OCT2020)	N/N
			MUSC Bone pain/ bone aches	2	01OCT2020	3/17	2	Yes		NA	R (17OCT2020)	N/N
			Myalgia/ muscle aches	2	01OCT2020	3/17	2	Yes		NA	R (17OCT2020)	N/N
			NERV Migraine/ worsening of migraine	2	01OCT2020	3/17	2	No	O	NA	R (17OCT2020)	N/N
			EYE Lacrimation increased/ watery eyes	2	05OCT2020	7/C	2	Yes		NA	N	N/N
EYE Vitreous detachment/ posterior vitreous detachment right eye	2	09NOV2020	42/C	2	No	O	NA	N	N/N			
16-55/ C459100 1 1028 10281158	3^	METAB	Impaired fasting glucose/ impaired fasting glucose	1	15SEP2020	6/C	2	No	O	NA/TC	N	N/N
			GASTR Nausea/ nausea	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
			GENRL Pain/ body aches	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1028 10281167	3^	INV	Body temperature increased/ increased body temperature	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
		NERV	Headache/ worsening headache	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
		GENRL	Injection site pain/ left arm soreness at injection site	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1028 10281170	3^	INV	Heart rate increased/ increased heart rate	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1028 10281174	3^	GENRL	Chills/ body chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ fever	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		MUSC	Arthralgia/ joint aches	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
			Myalgia/ muscle aches	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		NERV	Headache/ headache	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		NERV	Dizziness/ lightheadedness	1	14SEP2020	1/1	2	Yes		NA	R (14SEP2020)	N/Y
16-55/ C459100	3^	GENRL	Chills/ chills	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1028 10281177			Fatigue/ fatigue	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
			Pain/ body aches	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ fever	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1028 10281183	3^	GENRL	Fatigue/ fatigue	2	07OCT2020	2/3	2	Yes		NA	R (09OCT2020)	N/N
			Injection site pain/ left arm injection site pain	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
			Pain/ body aches	2	07OCT2020	2/3	2	Yes		NA	R (09OCT2020)	N/N
		INV	Body temperature increased/ elevated body temperature	2	07OCT2020	2/3	2	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ headache	2	07OCT2020	2/3	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1028 10281188	3^	GENRL	Injection site pain/ left arm soreness at injection site	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1028 10281198	3^	GENRL	Pain/ body aches	2	08OCT2020	1/4	2	Yes		NA/TC	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Pyrexia/ fever	2	09OCT2020	2/1	2	Yes		NA	R (09OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	10OCT2020	3/4	2	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1028 10281202	3^	INJ&P	Upper limb fracture/ left arm fracture	1	23SEP2020	6/C	2	No	O	NA/TCN	N	N/N
16-55/ C459100 1 1028 10281207	3^	GENRL	Pyrexia/ fever	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	14OCT2020	2/2	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1028 10281208	3^	INFEC	Tooth infection/ tooth infection left lower side	1	06OCT2020	16/13	2	No	O	NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 1028 10281213	3^	NERV	Presyncope/ vasovagal episode*		30SEP2020	1/1	1	No	O	NA	R (30SEP2020)	N/N
16-55/ C459100 1 1028 10281221	3^	GENRL	Injection site pain/ left arm soreness at injection site	1	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1028 10281223	3^	GENRL	Injection site pain/ left arm soreness at injection site	1	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	15OCT2020	2/C	2	Yes		NA	N	N/N
		INV	Body temperature increased/ increased body temperature	2	15OCT2020	2/C	2	Yes		NA	N	N/N
16-55/ C459100 1 1028 10281224	3^	GENRL	Fatigue/ fatigue	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1028 10281227	3^	GENRL	Injection site pain/ left arm soreness at injection site	1	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1028 10281228	3^	GENRL	Injection site pain/ left deltoid soreness at injection site	1	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
		MUSC	Arthralgia/ achiness in shoulders	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
		NERV	Headache/ headache	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	16OCT2020	3/2	2	Yes		NA	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INFEC	Trichomoniasis/ trichomoniasis	2	28OCT2020	15/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1028 10281237	3^	GENRL	Chills/ chills	2	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
			Pain/ body aches	2	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
			Pyrexia/ fever	2	20OCT2020	2/2	2	Yes		NA/TC	R (21OCT2020)	N/N
		NERV	Headache/ headache	2	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 1 1028 10281247	3^	GENRL	Injection site erythema/ redness injection site left deltoid	1	07OCT2020	1/15	2	Yes		NA	R (21OCT2020)	N/N
			Injection site swelling/ swelling injection site left deltoid	1	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
		GASTR	Vomiting/ vomiting	2	28OCT2020	1/2	2	Yes		NA	R (29OCT2020)	N/N
		GENRL	Pain/ body aches	2	28OCT2020	1/3	2	Yes		NA	R (30OCT2020)	N/N
		GENRL	Chills/ chills	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
		INV	Body temperature increased/ increased body temperature	2	29OCT2020	2/2	2	Yes		NA/TC	R (30OCT2020)	N/N
		NERV	Headache/ headache	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1030 10301030	3^	INFEC	Urinary tract infection/ urinary tract infection	1	05SEP2020	5/11	1	No	O	NA/TC	R (15SEP2020)	N/N
16-55/ C459100 1 1036 10361021	3^	GENRL	Chills/ Subject developed chills after injection	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
		RESP	Cough/ Subject developed cough after injection.	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C459100 1 1037 10371007	3^	GENRL	Fatigue/ FATIGUE	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 1 1037 10371008	3^	GENRL	Fatigue/ FATIGUE	2	09SEP2020	1/1	1	Yes		NA/TC	R (09SEP2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	09SEP2020	1/1	2	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C459100 1 1037 10371010	3^	RESP	Cough/ COUGH	1	06SEP2020	20/5	1	No	O	NA	R (10SEP2020)	N/N
16-55/ C459100	3^	GENRL	Pyrexia/ LOW GRADE FEVER	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1037 10371052		GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	2/30	1	No	CD	NA	R (23SEP2020)	N/N
		EAR	Ear pain/ EAR ACHE	2	18SEP2020	5/11	1	No	O	NA/TC	R (28SEP2020)	N/N
		GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	18SEP2020	5/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1037 10371067	3^	GENRL	Fatigue/ FATIGUE	2	14SEP2020	1/3	2	No	O	NA	R (16SEP2020)	N/N
16-55/ C459100 1 1037 10371076	3^	SKIN	Dermatitis allergic/ ALLERGIC RASH	1	26AUG2020	1/26	1	No	O	NA/TC	R (20SEP2020)	N/N
		IMMUN	Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	1	09SEP2020	15/12	2	No	O	NA/TC	R (20SEP2020)	N/N
		RESP	Wheezing/ WORSENING OF WHEEZING	1	09SEP2020	15/12	2	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C459100 1 1037 10371124	3^	GENRL	Pyrexia/ LOW GRADE FEVER	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C459100 1 1037 10371125	3^	GENRL	Chills/ CHILLS	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1037 10371170	3^	MUSC	Myalgia/ MUSCLE PAIN	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	2	29SEP2020	1/4	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1037 10371183	3^	GENRL	Injection site pain/ RIGHT ARM SORENESS INJECTION SITE	2	02OCT2020	2/14	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1037 10371216	3^	GENRL	Injection site induration/ INJECTION SITE REACTION LEFT ARM INDURATION	1	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ PAIN AT LEFT UPPER ARM INJECTION SITE	1	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	1	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Injection site erythema/ ERYTHEMA AT INJECTION SITE LEFT UPPER ARM	1	17SEP2020	3/4	2	Yes		NA/TCN	R (20SEP2020)	N/N
16-55/ C459100 1 1037 10371223	3^	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1037 10371236	3^	GASTR	Diarrhoea/ DIARRHEA	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1037 10371237	3^	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	2	09OCT2020	2/1	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1037 10371272	3^	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1037 10371277	3^	MUSC	Pain in extremity/ ARM PAIN LEFT	1	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
			Pain in jaw/ JAW PAIN LEFT	1	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Chills/ Chills	2	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 1037 10371290	3^	INFEC	Tooth infection/ TOOTH INFECTION	1	06OCT2020	12/8	2	No	O	NA/TC	RS (13OCT2020)	N/N
16-55/ C459100 1 1037 10371309	3^	MUSC	Muscle spasms/ LEFT LEG MUSCLE SPASMS	1	06OCT2020	7/6	2	No	O	NA	R (11OCT2020)	N/N
16-55/ C459100	3^	GASTR	Diarrhoea/ DIARRHEA	1	04OCT2020	3/6	1	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1037 10371317		INV	Blood glucose increased/ ELEVATED GLUCOSE	1	10OCT2020	9/9	1	No	O	NA	R (18OCT2020)	N/N
		SKIN	Rash/ RASH ON CHEST	1	17OCT2020	16/10	1	No	O	NA	R (26OCT2020)	N/N
16-55/ C459100 1 1038 10381002	3^	GENRL	Fatigue/ fatigue	1	09SEP2020	23/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1038 10381003	3^	GENRL	Chills/ Chills	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
			Pain/ Body aches	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
		GENRL	Fatigue/ fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Pain/ body aches	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1038 10381014	3^	GASTR	Nausea/ nausea	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Chills/ chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Pyrexia/ low grade fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1038 10381022	3^	GENRL	Chills/ Chills	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N
			Injection site erythema/ Redness at injection site	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N
			Injection site swelling/ swelling at injection site	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N
			Pain/ Body aching	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N
16-55/ C459100 1 1038 10381023	3^	GENRL	Fatigue/ fatigue	2	10SEP2020	2/8	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1038 10381091	3^	GENRL	Pain/ body aches	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
			Pyrexia/ fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1038 10381094	3^	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
			Injection site pain/ Injection Site Tenderness	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1038 10381095	3^	GENRL	Fatigue/ fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ injection site tenderness	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
			NERV Headache/ headache	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ Injection site tenderness	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1038 10381096	3^	GENRL	Chills/ chills	1	06SEP2020	3/2	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C459100 1 1038 10381121	3^	NERV	Restless legs syndrome/ Restless Leg Syndrome	2	29OCT2020	23/C	1	No	O	NA/TC	N	N/N
		RESP	Sleep apnoea syndrome/ Obstructive Sleep Apnea	2	29OCT2020	23/C	1	No	O	NA/TCN	N	N/N
16-55/ C459100 1 1038 10381131	3^	GASTR	Nausea/ nausea	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
		GENRL	Chills/ chills	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
			Pain/ aching	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ fever	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1038 10381133	3^	GENRL	Injection site pain/ injection site tenderness	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/Y
16-55/ C459100 1 1038 10381136	3^	GENRL	Injection site pain/ injection site tenderness	1	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	29SEP2020	9/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1039 10391004	3^	GENRL	Pain/ GENERALIZED ACHING	2	12SEP2020	2/C	2	Yes		NA	RG	N/N
16-55/ C459100 1 1039 10391016	3^	RESP	Oropharyngeal pain/ sore throat	1	25AUG2020	2/2	1	No	O	NA	R (26AUG2020)	N/N
16-55/ C459100 1 1039 10391026	3^	MUSC	Pain in extremity/ right upper arm pain	1	25AUG2020	1/5	1	Yes		NA	R (29AUG2020)	N/N
		RENAL	Dysuria/ dysuria,increased frequency	1	01SEP2020	8/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1039 10391036	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Asthenia/ generalized weakness	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
		NERV	Tension headache/ TENSION HEADACHE	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Chills/ chills	2	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ headache	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1039 10391045	3^	RESP	Oropharyngeal pain/ sore throat	1	28AUG2020	1/2	1	No	O	NA	R (29AUG2020)	N/N
16-55/ C459100 1 1039 10391058	3^	GENRL	Chills/ chills	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
			Fatigue/ fatigue	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		MUSC	Joint stiffness/ multiple joint stiffness	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Headache/ headache	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ injection site pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1039 10391067		GENRL	Injection site pain/ injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIAS	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1039 10391085	3^	GENRL	Fatigue/ fatigue	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1039 10391097	3^	GENRL	Chills/ CHILLS	2	25SEP2020	1/4	2	Yes		NA	R (28SEP2020)	N/N
			Fatigue/ FATIGUE	2	25SEP2020	1/5	2	Yes		NA	R (29SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
			Pain/ GENERALIZED ACHING	2	25SEP2020	1/4	2	Yes		NA/TC	R (28SEP2020)	N/N
			Pyrexia/ FEVER	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100 1 1039 10391104	3^	GENRL	Injection site pain/ injection site soreness	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1039 10391109	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1039 10391112	3^	GENRL	Injection site pain/ injection site pain	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
			Pyrexia/ fever	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1039 10391115	3^	GENRL	Injection site pain/ injection site pain	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ generalized muscle aches	1	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1039 10391118	3^	GENRL	Fatigue/ fatigue	2	01OCT2020	2/C	1	Yes		NA/TC	RG	N/N
			Injection site pain/ injection site soreness	2	01OCT2020	2/C	1	Yes		NA/TC	RG	N/N
			Pain/ body ache	2	01OCT2020	2/C	1	Yes		NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1039 10391119	3^	GENRL	Fatigue/ fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
			Injection site pain/ injection site soreness	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N	
			Pain/ bodyache	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N	
16-55/ C459100 1 1039 10391127	3^	GENRL	Fatigue/ fatigue	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N	
			Pain/ Aches-generalized	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
			Pyrexia/ fever	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N	
16-55/ C459100 1 1039 10391128	3^	GENRL	Fatigue/ FATIGUE	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N	
			NERV	Headache/ HEADACHE	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
			GENRL	Fatigue/ FATIGUE	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
				Pyrexia/ FEVER	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
			MUSC	Myalgia/ MYALGIAS	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1039 10391153	3^	NERV	Headache/ HEADACHE	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N
		INV	Body temperature increased/ Increased Body temperature	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1039 10391157	3^	NERV	Paraesthesia/ Finger tingling in injection arm	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1039 10391172	3^	GENRL	Fatigue/ fatigue	2	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N
		MUSC	Myalgia/ generalized muscle aches	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
		GENRL	Pyrexia/ fever	2	18OCT2020	3/1	1	Yes		NA	R (18OCT2020)	N/N
		GENRL	Injection site pain/ injection site soreness	1	03OCT2020	2/3	1	Yes		NA/TC	R (05OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
		GENRL	Pain/ generalized aching	2	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
		GENRL	Pyrexia/ fever	2	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ chills	2	25OCT2020	3/1	1	Yes		NA/TC	R (25OCT2020)	N/N
16-55/ C459100 1 1039 10391176	3^	GENRL	Fatigue/ fatigue	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		MUSC	Myalgia/ generalized muscle aches	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1039 10391180	3^	CARD	Palpitations/ pounding heart	1	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/Y
		NERV	Dizziness/ lightheaded	1	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/Y
16-55/ C459100 1 1042 10421028	3^	INJ&P	Chest injury/ bruised ribs	1	22AUG2020	20/13	2	No	O	NA/TC	R (03SEP2020)	N/N
16-55/ C459100 1 1042 10421041	3^	INFEC	Cystitis/ bladder infection	2	21SEP2020	27/15	2	No	O	NA/TC	R (05OCT2020)	N/N
16-55/ C459100 1 1042 10421109	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14AUG2020	1/1	1	Yes		NA	R (14AUG2020)	N/N
16-55/ C459100 1 1042 10421125	3^	GENRL	Chills/ Chills	2	14SEP2020	6/3	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1042 10421143	3^	GENRL	Fatigue/ Fatigue	2	14SEP2020	6/3	1	Yes		NA	R (16SEP2020)	N/N
			Pyrexia/ fever	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C459100 1 1042 10421158	3^	NERV	Headache/ headache	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
		GENRL	Pain/ Bodyache	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1042 10421161	3^	GENRL	Pyrexia/ Low Grade Fever	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
			NERV	Headache/ Headache	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)
		GENRL	Pain/ Bodyaches	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
			MUSC	Pyrexia/ Low Grade Fever	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)
16-55/ C459100 1 1042 10421198	3^	MUSC	Arthralgia/ SHOULDER PAIN RIGHT SIDE	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
			Neck pain/ NECK PAIN RIGHT SIDE	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1042 10421206	3^	GENRL	Chills/ Chills	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
			Pyrexia/ Fever	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 1 1042 10421216	3^	GENRL	Chills/ Chills	2	29SEP2020	1/1	1	Yes		NA	R (29SEP2020)	N/N
			Pyrexia/ Fever	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1042 10421222	3^	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1042 10421243	3^	INFEC	Ear infection/ lt ear infection	1	17SEP2020	7/C	1	No	O	NA/TC	N	N/N
		INV	Blood cholesterol increased/ High Cholesterol	1	24SEP2020	14/C	2	No	O	NA/TC	N	N/N
			Blood potassium decreased/ Low Potassium	1	24SEP2020	14/C	2	No	O	NA/TC	N	N/N
		GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1042 10421259	3^	BLOOD	Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
			MUSC	Arthralgia/ Joint Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			GENRL	Pyrexia/ Fever	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
			GENRL	Lymphadenopathy/ ENLARGED LYMPHNODES LEFT AXILLA	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1044 10441011	3^	MUSC	Injection site pain/ PAIN AT INJECTION SITE	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
16-55/ C459100 1 1044 10441011	3^	MUSC	Back pain/ low back pain	2	11SEP2020	2/1	1	No	O	NA	R (11SEP2020)	N/N	
16-55/ C459100 1 1044 10441028	3^	MUSC	Myalgia/ generalized Myalgias	2	16SEP2020	2/34	2	Yes		NA/TC	R (19OCT2020)	N/N	
16-55/ C459100 1 1044 10441029	3^	MUSC	Myalgia/ Myalgia	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N	
16-55/ C459100	3^	MUSC	Myalgia/ generalized Myalgia	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1044 10441037	3^	GENRL	Chills/ chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
1 1044 10441048			Fatigue/ fatigue	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ generalized Myalgias	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1044 10441054	3^	GENRL	Chills/ chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
			Fatigue/ FATIGUE	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ fever	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1044 10441057	3^	GENRL	Injection site pain/ Injection site pain	1	29AUG2020	1/2	2	Yes		NA	R (30AUG2020)	N/Y
		RENAL	Nephrolithiasis/ Renal Calculi	1	29AUG2020	1/36	2	No	O	NA	R (03OCT2020)	N/Y
16-55/ C459100 1 1044 10441058	3^	GASTR	Diarrhoea/ diarrhea	1	13SEP2020	3/1	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1044 10441060	3^	SKIN	Alopecia/ hair loss	2	05OCT2020	15/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1044 10441071	3^	GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ fever	2	23SEP2020	2/1	3	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Arthralgia/ joint pain	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
			Myalgia/ generalized Myalgia	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1044 10441076	3^	GENRL	Chills/ chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ generalized myalgia	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1044 10441077	3^	GASTR	Mouth ulceration/ ORAL ulcer	1	05SEP2020	3/2	1	No	O	NA/TC	R (06SEP2020)	N/N
16-55/ C459100 1 1044 10441079	3^	GENRL	Chills/ chills	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1044 10441086	3^	MUSC	Myalgia/ generalized myalgia	2	25SEP2020	1/32	1	Yes		NA	R (26OCT2020)	N/N
		GASTR	Diarrhoea/ diarrhea	1	05SEP2020	1/1	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C459100 1 1044 10441088	3^	GENRL	Fatigue/ fatigue	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N
		NERV	Headache/ headache	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	26SEP2020	2/5	1	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ injection site pain	2	26SEP2020	2/5	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1044 10441099	3^	MUSC	Myalgia/ generalized myalgia	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
		NERV	Headache/ headache	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
		INFEC	Gastroenteritis/ gastroenteritis	2	05OCT2020	7/1	1	No	O	NA	R (05OCT2020)	N/N
		INFEC	Furuncle/ boil inguinal area	1	22SEP2020	13/36	1	No	O	NA/TC	R (27OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1044 10441102	3^	INJ&P	Corneal abrasion/ Corneal abrasion (left)	1	27SEP2020	18/3	1	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C459100 1 1044 10441119	3^	GENRL	Chills/ chills	2	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N
			Fatigue/ fatigue	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		NERV	Headache/ headache	2	13OCT2020	1/3	1	Yes		NA/TC/TCN	R (15OCT2020)	N/N
16-55/ C459100 1 1044 10441123	3^	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ fever	1	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ headache	1	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1044 10441127	3^	GENRL	Chills/ chills	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
			Fatigue/ General fatigue	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ fever	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1044 10441129	3^	MUSC	Myalgia/ Myalgia (mild) generalized	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1044 10441133	3^	GENRL	Pyrexia/ FEVER	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgia GENERALIZED	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1044 10441139	3^	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/1	1	Yes		NA/TC	R (13OCT2020)	N/N
		GENRL	Pyrexia/ fever	2	14OCT2020	2/1	2	Yes		NA	R (14OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
			Injection site pain/ injection site pain	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		NERV	Headache/ headache	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1044 10441142	3^	GENRL	Chills/ chills	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N	
			Pyrexia/ fever	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
		SKIN	Angioedema/ Angioedema face	2	16OCT2020	3/2	1	Yes		NA	R (17OCT2020)	N/N	
		3^	GENRL	Injection site pain/ Injection site pain	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
			GENRL	Chills/ chills	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
			NERV	Headache/ Headache	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
		3^	INFEC	Otitis externa/ otitis externa (left ear)	1	27SEP2020	4/8	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 1044 10441152	3^†	GASTR	Mouth ulceration/ oral Ulcer	2	24OCT2020	6/3	1	No	O	NA	R (26OCT2020)	N/N	
			Stomatitis/ Stomatitis	2	24OCT2020	6/3	1	No	O	NA	R (26OCT2020)	N/N	
16-55/ C459100 1 1044 10441153	3^	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/C	1	Yes		NA	RG	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1044 10441157	3^	GENRL	Injection site erythema/ redness to injection site	2	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
			Pyrexia/ fever	2	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
		GENRL	Chills/ Chills	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1044 10441165	3^		Pyrexia/ Fever	2	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		GENRL	Injection site pain/ injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
		GENRL	Pyrexia/ Fever	1	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
		MUSC	Myalgia/ myalgia	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
		GASTR	Nausea/ nausea	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
GENRL			Chills/ chills	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
			Injection site pain/ injection site pain	2	09NOV2020	1/C	1	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ fever	2	09NOV2020	1/2	3	Yes		NA/TC	R (10NOV2020)	N/N
		MUSC	Myalgia/ myalgia	2	09NOV2020	1/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1046 10461046	3^	BLOOD	Lymphadenopathy/ Swollen Lymph Node on left side of Neck	2	14SEP2020	7/7	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C459100 1 1046 10461091	3^	NERV	Migraine/ Migraine	2	15SEP2020	2/3	2	No	O	NA	R (17SEP2020)	N/N
16-55/ C459100 1 1046 10461145	3^	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	05OCT2020	15/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1046 10461153	3^	GASTR	Diarrhoea/ Diarrhea	1	05SEP2020	5/C	3	No	O	NA	N	N/N
		GENRL	Fatigue/ Fatigue	1	05SEP2020	5/C	3	No	O	NA	N	N/N
			Pyrexia/ Fever	1	05SEP2020	5/4	3	No	O	NA	R (08SEP2020)	N/N
16-55/ C459100 1 1047 10471010	3^	GENRL	Injection site pain/ soreness of injection site left deltoid	1	02SEP2020	14/C	1	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site erythema/ Redness at injection site left deltoid	2	08SEP2020	1/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1047 10471018	3^	GENRL	Injection site pain/ Soreness Left arm post injection	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1047 10471025	3^	GENRL	Pain/ body aches	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		NERV	Headache/ headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1047 10471033	3^	GENRL	Injection site pain/ injection site Soreness Left Deltoid	1	25AUG2020	4/1	1	Yes		NA	R (25AUG2020)	N/N
		GENRL	Injection site pain/ injection site pain left arm	2	12SEP2020	1/3	2	Yes		NA	R (14SEP2020)	N/N
			Injection site pruritus/ left arm itchiness at injection site	2	12SEP2020	1/3	2	Yes		NA	R (14SEP2020)	N/N
			Injection site swelling/ left arm swollen at injection site	2	12SEP2020	1/3	2	Yes		NA	R (14SEP2020)	N/N
16-55/ C459100 1 1047 10471040	3^	GENRL	Pain/ body aches	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ 100.4 fever	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1047 10471041	3^	GENRL	Pyrexia/ 100.4 fever	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ generalized muscles aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1047 10471057	3^	GENRL	Pyrexia/ low grade temp post injection 99.9	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1047 10471061	3^	GENRL	Pain/ Body Aches generalized	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ Fever 102	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ Fever 103.0	2	17SEP2020	2/1	3	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1047 10471064	3^	GENRL	Pain/ Body aches generalized	2	17SEP2020	2/C	1	Yes		NA	N	N/N
			Pyrexia/ Temp 101	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1047 10471069	3^	GENRL	Pain/ Body aches generalized	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1047 10471070	3^	GENRL	Injection site pain/ Injection Site Soreness	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
			Pain/ Body aches generalized	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1047 10471081	3^	GASTR	Nausea/ Nausea	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1047 10471093	3^	IMMUN	Seasonal allergy/ Seasonal Allergies	1	02SEP2020	3/C	1	No	O	NA	N	N/N
		RESP	Oropharyngeal pain/ intermittent Sore throat	1	02SEP2020	3/C	1	No	O	NA	N	N/N
		GENRL	Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1047 10471095	3^	GENRL	Injection site pain/ left injection site shoulder pain.	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
			MUSC	Neck pain/ Neck Pain	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1047 10471106	3^	GENRL	Fatigue/ Fatigue	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	
				Injection site swelling/ Injection site swelling	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
				Chills/ Chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1047 10471128	3^	GENRL	Headache/ Headaches	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
				Chills/ Chills	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
				Pain/ Bodyaches	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1047 10471128	3^	GENRL	Pyrexia/ Fever 101.0	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N	
			NERV	Headache/ Headache	2	24SEP2020	2/8	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1047 10471133	3^	RESP	Paranasal sinus discomfort/ Sinus Pressure	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
		GENRL	Pain/ Bodyaches	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1047 10471143	3^	INV	Body temperature increased/ Increased body temperature 100.0	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		MUSC	Arthralgia/ Elbow pain right arm	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 1 1047 10471172	3^	GENRL	Arthralgia/ wrist pain right arm	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
			Myalgia/ muscle pain right arm	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
			Chills/ Chills	1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N
		RENAL	Fatigue/ Fatigue	1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N
			Injection site pain/ Injection site soreness	1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N
			Nephrolithiasis/ Kidney Stone, Right Side	2	05NOV2020	37/4	2	No	O	NA	R (08NOV2020)	N/N
16-55/ C459100	3^	GASTR	Diarrhoea/ Diarrhea	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1047 10471174		GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1047 10471180	3^	GENRL	Injection site pain/ Soreness at injection site	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1047 10471186	3^	EAR	Ear discomfort/ Ear pressure	2	05OCT2020	1/C	1	No	O	NA/TC	RG	N/N
		GENRL	Chills/ Chills	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		RESP	Rhinitis allergic/ Allergic Rhinitis	1	05OCT2020	25/C	1	No	O	NA/TC	RG	N/N
		EAR	Ear pain/ Bilateral Otalgia	2	06OCT2020	2/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1047 10471201	3^	GENRL	Injection site pain/ Left Arm soreness post injection	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C459100 1 1047 10471203	3^	UNC	FATIGUE@@/ Fatigue*		14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
			LEFT ARM PAIN AT INJECTION SITE@@/ Left arm pain at injection site*		14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)		
16-55/ C459100 1 1047 10471217	3^	UNC	FATIGUE@@/ Fatigue	1	12OCT2020	29/2	1	Yes		NA	R (13OCT2020)	N/N		
			LEFT ARM PAIN AT INJECTION SITE@@/ Left arm pain at injection site	1	12OCT2020	29/2	1	Yes		NA	R (13OCT2020)	N/N		
		UNC	SPRAINED LEFT FOOT@@/ Sprained Left Foot	2	09NOV2020	29/C	2	No	O	NA	RG	N/N		
			SPRAINED RIGHT FOOT@@/ Sprained Right Foot	2	09NOV2020	29/C	2	No	O	NA	RG	N/N		
		SKIN	Blister/ left torso blisters	2	12OCT2020	4/25	1	No	O	NA	R (05NOV2020)	N/N		
			Rash/ left torso rash	2	12OCT2020	4/25	1	No	O	NA	R (05NOV2020)	N/N		
		16-55/ C459100 1 1047 10471223	3^	GENRL	Chills/ Chills	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
				GENRL	Pain/ body aches	1	08OCT2020	23/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1047 10471225	3^	INV	Body temperature increased/ increased body temperture 99.1	1	08OCT2020	23/2	1	Yes		NA	R (09OCT2020)	N/N		
		EYE	Photophobia/ Light sensitivity eyes	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N		
		GASTR	Nausea/ Nausea	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1047 10471232	3^	GENRL	Pain/ Bodyaches	2	06OCT2020	2/9	1	Yes		NA	R (14OCT2020)	N/N
		GENRL	Pyrexia/ Fever 102.6	2	07OCT2020	3/1	3	Yes		NA	R (07OCT2020)	N/N
		GENRL	Injection site pain/ Injection site soreness left arm*		17SEP2020	1/8	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1047 10471241	3^	GASTR	Diarrhoea/ Diarrhea	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1047 10471244	3^		Nausea/ Nausea	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Soreness	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
			Pain/ Bodyaches	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
			Pyrexia/ Low Grade Fever 100.4	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
		NERV	Headache/ Headaches	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
		GENRL	Injection site pain/ Injection site soreness left arm*		18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1047 10471254		GENRL	Fatigue/ Fatigue	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1047 10471255	3^	GENRL	Injection site pain/ Soreness at injection site left arm*		21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
			Pyrexia/ fever 101.6	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1047 10471266	3^	GASTR	Diarrhoea/ diarrhea (mild)	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Chills/ chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1047 10471267	3^	GENRL	Injection site pain/ soreness at injection site*		22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
			Pyrexia/ low grade temperature (99.1)	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		MUSC	Myalgia/ muscle aches	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1047 10471275	3^	GENRL	Chills/ chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
			Pain/ body aches	2	14OCT2020	1/5	2	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1048 10481004	3^	INJ&P	Muscle strain/ THORACIC MUSCLE STRAIN	2	24SEP2020	23/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1048 10481020	3^	SKIN	Pruritus/ PRURITIS - LEFT FOOT	2	05OCT2020	26/2	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1048 10481025	3^	GENRL	Fatigue/ fatigue	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		MUSC	Myalgia/ New muscle pain, generalized	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1048 10481032	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	26AUG2020	2/5	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 1 1048 10481040	3^	SKIN	Rash/ RASH LEFT ANTECUBITAL	1	27AUG2020	1/4	1	No	O	NA	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1048 10481044	3^	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1048 10481044	3^	GENRL	Cyst/ CYST ON LEFT GROIN	2	05OCT2020	20/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1048 10481055	3^	GENRL	Fatigue/ fatigue	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N
16-55/ C459100 1 1048 10481065	3^	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1048 10481075	3^	GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Chills/ Chills	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
			Pain/ body aches	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		INFEC	Nasopharyngitis/ common cold	2	18OCT2020	26/C	1	No	O	NA	N	N/N
16-55/ C459100	3^	GENRL	Fatigue/ FATIGUE	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1048 10481079			Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1048 10481083	3^	GENRL	Chills/ chills	1	06SEP2020	4/7	1	Yes		NA	R (12SEP2020)	N/N
			Fatigue/ Fatigue	1	06SEP2020	4/7	1	Yes		NA	R (12SEP2020)	N/N
		NERV	Dizziness/ dizziness	1	06SEP2020	4/7	1	Yes		NA	R (12SEP2020)	N/N
			Headache/ headaches	1	06SEP2020	4/7	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1048 10481086	3^	GENRL	Injection site pain/ muscle pain at injection site	1	04SEP2020	2/2	2	Yes		NA	R (05SEP2020)	N/N
		SKIN	Night sweats/ Profuse night sweating	1	04SEP2020	2/2	2	Yes		NA	R (05SEP2020)	N/N
		GASTR	Nausea/ nausea	1	05SEP2020	3/3	1	Yes		NA	R (07SEP2020)	N/N
		NERV	Headache/ headache	1	05SEP2020	3/6	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Pain/ body aches	2	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100	3^	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	20SEP2020	17/C		No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1048 10481088	3^	GENRL	Fatigue/ FATIGUE	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
1 1048 10481106			Pyrexia/ FEVER	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1048 10481125	3^	INJ&P	Tooth fracture/ CRACKED TOOTH	2	05OCT2020	5/5	2	No	O	NA	R (09OCT2020)	N/N
16-55/ C459100 1 1048 10481132	3^	GENRL	Fatigue/ FATIGUE	1	12SEP2020	2/11	1	Yes		NA/TCN	R (22SEP2020)	N/N
16-55/ C459100 1 1052 10521160	3^	NERV	Headache/ intermittent headaches	1	23SEP2020	1/C	1	No	O	NA	N	N/Y
16-55/ C459100 1 1054 10541002	3^	GENRL	Chills/ one episode of chills	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ soreness L arm injection site	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1054 10541003	3^	NERV	Headache/ headache	2	09SEP2020	1/1	1	Yes		NA/TC	R (09SEP2020)	N/N
1 1054 10541005		MUSC	Arthralgia/ L shoulder pain	2	04OCT2020	26/7	2	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1054 10541011	3^	GENRL	Fatigue/ fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Injection site erythema/ redness at L arm injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Injection site pain/ soreness at L arm injection site	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
			Injection site swelling/ swelling at L arm injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1054 10541012	3^	GASTR	Diarrhoea/ diarrhea - 1 episode	2	17SEP2020	7/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1054 10541014	3^	GASTR	Nausea/ nausea	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Chills/ chills	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1054 10541018	3^	GENRL	Injection site pain/ muscle ache at injection site, L arm	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N	
			Injection site pain/ pain at injection site L arm	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N	
	16-55/ C459100 1 1054 10541032	3^	GENRL	Injection site pain/ pain L arm at injection site	1	23AUG2020	2/3	1	Yes		NA	R (25AUG2020)	N/N
				MUSC	Back pain/ low back pain	1	23AUG2020	2/4	1	Yes		NA/TC	R (26AUG2020)
		GENRL	Injection site pain/ pain injection site	2	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N	
			GASTR	Nausea/ nausea	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
			GENRL	Fatigue/ fatigue	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
			GENRL	Fatigue/ fatigue	1	23AUG2020	2/13	1	Yes		NA	R (04SEP2020)	N/N
	16-55/ C459100 1 1054 10541035	3^	INFEC	Chronic sinusitis/ worsening of chronic sinusitis	2	24SEP2020	15/C	1	No	O	NA/TC/TCN	N	N/N
	16-55/ C459100	3^	GENRL	Injection site pain/ soreness at injection site (LUE)	1	24AUG2020	1/5	1	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1054 10541043		GENRL	Chills/ chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
			Pyrexia/ fever	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		NERV	Headache/ headache	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1054 10541050	3^	GENRL	Injection site pain/ pain at injection site, L deltoid	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		MUSC	Myalgia/ muscle ache L upper arm	1	28AUG2020	3/2	1	Yes		NA	R (29AUG2020)	N/N
		NERV	Headache/ headache	2	30SEP2020	15/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1054 10541054	3^	GENRL	Pyrexia/ subjective fever	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N
		GENRL	Chest pain/ chest pain with deep inspiration	1	29AUG2020	4/2	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 1 1054 10541058	3^	GENRL	Injection site pain/ soreness L arm injection site	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100	3^	GASTR	Vomiting/ vomiting	1	03SEP2020	8/2	1	No	O	NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1054 10541065	3^	NERV	Headache/ Headache	1	28AUG2020	1/2	2	Yes		NA/TC/TCN	R (29AUG2020)	N/N
1 1054 10541067		NERV	Headache/ headache	2	18SEP2020	1/2	2	Yes		NA/TC	R (19SEP2020)	N/N
		EAR	Hypoacusis/ decreased hearing R ear	2	20SEP2020	3/C	2	No	O	NA/TC	RG	N/N
			Tinnitus/ Tinnitus R ear	2	20SEP2020	3/C	2	No	O	NA/TC	N	N/N
			Vertigo/ vertigo	2	20SEP2020	3/3	1	No	O	NA	R (22SEP2020)	N/N
		EAR	Ear disorder/ fluid R ear	2	22SEP2020	5/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1054 10541068	3^	GENRL	Pyrexia/ fever	1	17SEP2020	21/1	3	No	O	NA	R (17SEP2020)	N/N
16-55/ C459100 1 1054 10541069	3^	GENRL	Chills/ intermittent chills	1	28AUG2020	1/8	1	Yes		NA	R (04SEP2020)	N/N
			Pain/ diffuse body aches	1	28AUG2020	1/4	1	Yes		NA	R (31AUG2020)	N/N
		GENRL	Fatigue/ fatigue	1	29AUG2020	2/2	2	Yes		NA	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1054 10541070	3^	VASC	Hot flush/ hot flashes (worsening)	1	29AUG2020	2/8	1	Yes		NA	R (05SEP2020)	N/N
		INV	Blood testosterone decreased/ low testosterone	2	16OCT2020	8/C	1	No	O	NA	N	N/N
		GENRL	Injection site pain/ pain L arm injection site	1	28AUG2020	1/4	1	Yes		NA	R (31AUG2020)	N/N
16-55/ C459100 1 1054 10541073	3^	GENRL	Chills/ chills	1	18SEP2020	22/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		SKIN	Rash/ rash, L arm	1	11SEP2020	15/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1054 10541074	3^	SKIN	Pruritus/ intermittent itching umbilical area	1	04SEP2020	8/16	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ chills	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1054 10541078	3^	GENRL	Pain/ body ache	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Dizziness/ dizziness - intermittent	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Headache/ headache	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1054 10541080	3^	INJ&P	Road traffic accident/ road accident	2	19OCT2020	29/1	1	No	O	NA	R (19OCT2020)	N/N
		MUSC	Coccydynia/ pain in tail bone	2	19OCT2020	29/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1054 10541087	3^	GENRL	Injection site pain/ site injection pain	1	01SEP2020	1/4	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1054 10541089	3^	GENRL	Asthenia/ low energy	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ soreness L arm injection site	2	23SEP2020	2/5	1	Yes		NA	R (27SEP2020)	N/N
			Pain/ diffuse body aches	2	23SEP2020	2/2	2	Yes		NA/TC	R (24SEP2020)	N/N
			Pyrexia/ subjective fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1054 10541090	3^	GENRL	Chills/ chills	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		MUSC	Pain in extremity/ soreness R arm	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1054 10541096	3^	NERV	Headache/ headache	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Pain/ diffuse soreness	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
			Chills/ intermittent chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Fatigue/ fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ fever	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1054 10541097	3^	BLOOD	Iron deficiency anaemia/ anemia, iron deficiency	2	08OCT2020	16/C	1	No	CD	NA/TC	N	N/N
		GENRL	Fatigue/ fatigue	1	14SEP2020	13/34	1	Yes		NA	R (17OCT2020)	N/N
		NERV	Somnolence/ sleepiness	1	14SEP2020	13/34	1	Yes		NA	R (17OCT2020)	N/N
		VASC	Hot flush/ hot flashes	1	14SEP2020	13/23	1	Yes		NA	R (06OCT2020)	N/N
		NERV	Headache/ intermittent headache	1	18SEP2020	17/32	1	Yes		NA/TC	R (19OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		ENDO	Hypothyroidism/ hypothyroidism	2	25SEP2020	3/C	1	No	O	NA	N	N/N
		METAB	Dyslipidaemia/ dyslipidemia	2	25SEP2020	3/C	1	No	O	NA	N	N/N
		INFEC	Urinary tract infection/ UTI	2	03OCT2020	11/3	1	No	O	NA/TC/TCN	R (05OCT2020)	N/N
		INFEC	Pyelonephritis/ pyelonephritis	2	05OCT2020	13/13	2	No	O	NA/TC	R (17OCT2020)	N/N
		GASTR	Diverticulum intestinal/ diverticulosis of the colon	2	06OCT2020	14/C	1	No	O	NA	N	N/N
		RESP	Lung infiltration/ nodular interstitial infiltrate, RLL of lung	2	06OCT2020	14/C	1	No	O	NA	N	N/N
		REPRO	Nipple pain/ bilateral nipple pain	2	15OCT2020	23/13	1	No	O	NA	R (27OCT2020)	N/N
16-55/ C459100 11054 10541098	3^	GENRL	Injection site pain/ pain R arm injection site	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 11054 10541101	3^	GENRL	Injection site pain/ pain L arm injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Chills/ chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ low grade fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100	3^	GENRL	Pyrexia/ fever - subjective	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1054 10541104	3^	GENRL	Injection site pain/ soreness R arm injection site	1	03SEP2020	1/5	1	Yes		NA	R (07SEP2020)	N/N
1 1054 10541108	3^	GASTR	Diarrhoea/ diarrhea	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N
1 1054 10541111			Nausea/ nausea	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Pain/ diffuse body aches	2	25SEP2020	2/2	2	Yes		NA/TC	R (26SEP2020)	N/N
		METAB	Decreased appetite/ decreased appetite	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
		NERV	Dysgeusia/ metallic taste	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
			Migraine/ migraine headache	2	25SEP2020	2/3	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C459100 1 1054 10541113	3^	GENRL	Injection site pain/ site injection pain	1	05SEP2020	3/6	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1054 10541115	3^	GENRL	Injection site pain/ tenderness L arm injection site	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 11054 10541119	3^	NERV	Injection site pruritus/ itching L arm injection site	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N	
			MUSC	Arthralgia/ joint aches	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
			GENRL	Injection site bruising/ bruising L arm injection site	1	06SEP2020	3/6	1	Yes		NA	R (11SEP2020)	N/N
			GENRL	Chills/ chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
				Fatigue/ fatigue	2	26SEP2020	2/1	2	Yes		NA	R (26SEP2020)	N/N
				Pain/ generalized body aches	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
				Pyrexia/ subjective fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
			MUSC	Arthralgia/ bilateral hip joint ache	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
			SKIN	Night sweats/ night sweats	2	27SEP2020	3/1	1	Yes		NA	R (27SEP2020)	N/N
						Headache/ headache	2	19OCT2020	25/1	1	No	O	NA/TC
16-55/ C459100 11054 10541121	3^	GASTR	Diarrhoea/ diarrhea, single episode	1	08SEP2020	5/1	1	No	O	NA	R (08SEP2020)	N/N	
		GENRL	Chills/ chills	1	08SEP2020	5/1	1	No	O	NA	R (08SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1054 10541122	3^	RESP	Nasal congestion/ nasal congestion	1	27SEP2020	20/2	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C459100 1 1054 10541135	3^	MUSC	Back pain/ low back soreness	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Back pain/ low back soreness	2	30SEP2020	2/1	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1054 10541140	3^	GENRL	Injection site bruising/ bruise L arm injection site	1	11SEP2020	2/21	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1054 10541141	3^	GENRL	Injection site pain/ muscle pain at injection site, L arm	1	10SEP2020	1/4	1	Yes		NA/TC	R (13SEP2020)	N/N
		NERV	Headache/ headache*		10SEP2020	1/4	1	No	O	NA	R (13SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	30SEP2020	1/5	2	Yes		NA/TC	R (04OCT2020)	N/N
		GASTR	Nausea/ nausea	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Chills/ chills	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ fever	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1054 10541144	3^	MUSC	Back pain/ upper back ache	2	01OCT2020	2/1	2	Yes		NA/TC	R (01OCT2020)	N/N
		GASTR	Abdominal pain upper/ epigastric pain	1	12SEP2020	2/5	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1054 10541148	3^	GENRL	Fatigue/ fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Myalgia/ myalgia	1	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		GENRL	Injection site pain/ soreness L arm injection site	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
		NERV	Headache/ headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		GASTR	Nausea/ nausea	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Chills/ chills	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
			Injection site pain/ soreness at injection site	2	02OCT2020	1/9	1	Yes		NA	R (10OCT2020)	N/N
			Pyrexia/ fever	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
NERV	Headache/ headache	2	02OCT2020	1/2	2	Yes		NA/TC	R (03OCT2020)	N/N		
	SKIN	Rash/ rash upper abdomen	2	02OCT2020	1/5	1	Yes		NA	R (06OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1054 10541152	3^	GASTR	Nausea/ intermittent nausea	2	07OCT2020	6/4	1	Yes		NA	R (10OCT2020)	N/N
			Retching/ dry heaves	2	07OCT2020	6/1	1	Yes		NA	R (07OCT2020)	N/N
		MUSC	Musculoskeletal stiffness/ neck stiffness	2	07OCT2020	6/1	1	Yes		NA	R (07OCT2020)	N/N
				2	07OCT2020	6/10	2	Yes		NA	R (16OCT2020)	N/N
		NERV	Headache/ headache	2	07OCT2020	6/3	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Feeling abnormal/ brain fog	2	11OCT2020	10/1	1	No	O	NA	R (11OCT2020)	N/N
		GENRL	Feeling abnormal/ brain fog	2	13OCT2020	12/1	1	No	O	NA	R (13OCT2020)	N/N
		GENRL	Pyrexia/ fever	1	19SEP2020	6/1	1	Yes		NA	R (19SEP2020)	N/N
		NERV	Motor dysfunction/ L C7 motor dysfunction	2	OCT2020	1/C	1	No	O	NA/TCN	N	N/N
			Radiculopathy/ worsening of radiculopathy, both upper extremities	2	OCT2020	1/C	2	No	O	NA/TC/TCN	N	N/N
		EYE	Eye irritation/ burning sensation in eyes	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
		GENRL	Chills/ chills	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1054 10541157	3^	GENRL	Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ subjective fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
			MUSC Myalgia/ diffuse muscle aches	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
			NERV Headache/ headache	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
		GENRL	Injection site pain/ site injection pain, L arm	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		GENRL	Injection site pain/ soreness at R arm injection site	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GASTR	Nausea/ nausea	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1054 10541160	3^	GENRL	Chills/ chills	2	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Injection site pain/ muscle ache at R arm injection site	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Injection site pain/ soreness R arm injection site	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1054 10541174	3^	GENRL	Injection site pain/ soreness R arm injection site	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)		
16-55/ C459100 1 1054 10541182	3^	NERV	Headache/ headache	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N		
			Somnolence/ drowsiness	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N		
		GENRL	Injection site pain/ soreness R arm injection site	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N		
				2	08OCT2020	1/6	2	Yes		NA	R (13OCT2020)	N/N		
		GENRL	Fatigue/ fatigue	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N		
				2	Pain/ generalized body aches	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
						09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
		BLOOD	intermittent low grade feverw	1	06OCT2020	14/C	1	No	O	NA	N	N/N		
				GASTR	Dry mouth/ dry mouth	2	19OCT2020	5/6	1	Yes		NA/TCN	R (24OCT2020)	N/N
						2	19OCT2020	5/6	1	Yes		NA/TCN	R (24OCT2020)	N/N
GENRL	Thirst/ increased thirst			2	19OCT2020	5/6	1	Yes		NA/TCN	R (24OCT2020)	N/N		
16-55/ C459100 1 1054 10541184	3^	RESP	Epistaxis/ epistaxis R nostril	1	14OCT2020	22/1	1	No	O	NA	R (14OCT2020)	N/N		
16-55/ C459100	3^	GENRL	Injection site pruritus/ Itching at injection site	2	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/Y		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1055 10551007	3^	BLOOD	Lymphadenopathy/ Left supraclavicular adenopathy	2	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
1 1055 10551012	3^	RESP	Oropharyngeal pain/ Sore throat	2	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
1 1055 10551034		GENRL	Injection site pruritus/ Itching at injection site	2	03SEP2020	3/5	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C459100 1 1055 10551051	3^	GENRL	Chills/ Chills	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain, left	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
		GENRL	Chills/ Chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1055 10551054	3^	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551057	3^	NERV	Headache/ Headache	1	17AUG2020	1/2	1	Yes		NA/TC	R (18AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	17AUG2020	1/7	2	Yes		NA	R (23AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
		GENRL	Chills/ Chills	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1055 10551058	3^	GENRL	Injection site pain/ Injection Site Pain	2	08SEP2020	1/7	1	Yes		NA/TC	R (14SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 1 1055 10551067	3^	MUSC	Myalgia/ Myalgias	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551071	3^	GENRL	Injection site pain/ Injection site pain	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C459100 1 1055 10551072	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	07SEP2020	20/6	2	No	O	NA/TC	R (12SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	14SEP2020	1/4	1	Yes		NA/TC	R (17SEP2020)	N/N
		MUSC	Arthralgia/ Joint Pains	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	2/4	1	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	1	20AUG2020	2/3	1	Yes		NA/TC	R (22AUG2020)	N/N
16-55/ C459100 1 1055 10551075	3^	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/5	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ Chills	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1055 10551076	3^	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Chills/ Chills	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1055 10551078	3^	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/3	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C459100 1 1055 10551080	3^	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
		GENRL	Pyrexia/ Fever	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		RESP	Productive cough/ Productive cough	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
		RESP	Productive cough/ Productive cough	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551084	3^	GENRL	Fatigue/ Fatigue	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
			Feeling hot/ Warm feeling of neck and head	1	20AUG2020	1/2	1	Yes		NA/TC	R (21AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
			Pyrexia/ Low grade fever	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C459100 1 1055 10551086	3^	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		UNC	BLEPHARITIS@@/ Blepharitis	2	20SEP2020	12/51	1	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C459100 1 1055 10551089	3^	GENRL	Injection site pain/ Pain at injection site, left	1	21AUG2020	1/5	1	Yes		NA	R (25AUG2020)	N/N
		GENRL	Injection site erythema/ Erythema at injection site	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1055 10551092	3^	GENRL	Injection site erythema/ Erythema at injection site	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
			Injection site pain/ Pain at injection site	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N	
		GENRL	Chills/ Chills	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N	
			Fatigue/ Fatigue	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N		
	GENRL	Injection site pain/ Injection Site Pain	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N		
	16-55/ C459100 1 1055 10551103	3^	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
			NERV	Headache/ Headache	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
GENRL			Pyrexia/ Fever	1	25AUG2020	1/3	2	Yes		NA/TC	R (27AUG2020)	N/N	
NERV			Headache/ Headache	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N	
GENRL	Chills/ Chills	2	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N			
			Injection site pain/ Injection Site Pain	2	15SEP2020	1/8	2	Yes		NA/TC	R (22SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1055 10551104	3^	GENRL	Pyrexia/ Fever	2	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N	
			NERV	Headache/ Headache	2	15SEP2020	1/4	1	Yes		NA/TC	R (18SEP2020)	N/N
			Fatigue/ Fatigue	1	25AUG2020	1/4	2	Yes		NA	R (28AUG2020)	N/N	
			SKIN	Hyperhidrosis/ Diaphoresis	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
			GENRL	Fatigue/ Fatigue	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
			NERV	Dizziness/ Dizzy	2	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1055 10551105	3^	GENRL	GASTR	Diarrhoea/ Diarrhea	2	18SEP2020	3/3	1	Yes	NA	R (20SEP2020)	N/N	
			Fatigue/ Fatigue	2	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C459100 1 1055 10551115	3^	GENRL	NERV	Pyrexia/ Fever	2	15SEP2020	1/3	1	Yes	NA/TC	R (17SEP2020)	N/N	
			NERV	Disturbance in attention/ Difficulty concentrating	2	16SEP2020	2/11	2	Yes		NA	R (26SEP2020)	N/N
			Fatigue/ Fatigue	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551116	3^	NERV	Injection site pain/ Pain at injection site	1	26AUG2020	1/6	2	Yes		NA/TC	R (31AUG2020)	N/N
			Dizziness/ Dizzy	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/Y
		GENRL	Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/Y
			Fatigue/ Fatigue	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Injection site pain/ Injection site pain	2	16SEP2020	1/5	2	Yes		NA	R (20SEP2020)	N/N
			Headache/ Headache	2	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N
		GENRL	Chills/ Chills	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Injection site erythema/ Injection site redness	2	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pruritus/ Injection site itching	2	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Chills/ Chills	1	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
SKIN	Hyperhidrosis/ Diaphoresis	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N		
GENRL	Chills/ Chills	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N		
GENRL	Pyrexia/ Fever	2	14SEP2020	1/2	3	Yes		NA/TC	R (15SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551121	3^	MUSC	Myalgia/ Myalgias	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 1 1055 10551125	3^	GENRL	Injection site pain/ Injection site pain	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
		SKIN	Rash/ Rash on left thigh, left calf, left forearm, right foot	1	30AUG2020	4/22	2	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100 1 1055 10551131	3^	GENRL	Chills/ Chills	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
		SKIN	Pruritus/ Itching on left anterior thigh	2	28SEP2020	1/1	1	Yes		NA	R (28SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551136	3^	GENRL	Chills/ Chills	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	28AUG2020	1/4	1	Yes		NA	R (31AUG2020)	N/N
		GASTR	Oral pain/ Oral Pain	1	14SEP2020	18/9	1	No	O	NA/TC	R (22SEP2020)	N/N
		INFEC	Tooth abscess/ Dental Abscess	1	14SEP2020	18/1	1	No	O	NA/TC	R (14SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ Headache	2	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1055 10551143	3^	INFEC	Tooth abscess/ Dental abscess	2	01OCT2020	16/14	2	No	O	NA/TC	R (14OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551144	3^	GENRL	Injection site pain/ Injection Site Pain	2	18SEP2020	1/4	2	Yes		NA/TC	R (21SEP2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	1/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Chills/ Chills	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
			Fatigue/ Fatigue	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
			Injection site pain/ Injection Site Pain	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Pain	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
		GENRL	Chills/ Chills	2	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
			Fatigue/ Fatigue	2	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1055 10551145	3^	MUSC	Myalgia/ Myalgias	2	18SEP2020	1/3	2	Yes		NA/TC	R (20SEP2020)	N/N
		NERV	Headache/ Headaches	2	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
		GASTR	Dysphagia/ Dysphagia	1	AUG2020	1/C	1	No	O	P	N	N/N
		NERV	Cerebral capillary telangiectasia/ Cerebral Capillary telangiectasia	1	26SEP2020	30/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551146	3^	MUSC	Pain in extremity/ Right upper extremity pain	1	10OCT2020	44/C	1	No	O	NA	N	N/N
		GASTR	Diarrhoea/ Diarrhea	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
			Injection site pain/ Injection Site Pain	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
		MUSC	Myalgia/ Myalgias	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1055 10551151	3^	MUSC	Myalgia/ Myalgias	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/5	2	Yes		NA	R (04SEP2020)	N/N
		NEOPL	Lipoma/ Lipoma	1	14SEP2020	15/C	1	No	O	NA	N	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1055 10551161	3^	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	2/3	2	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551162	3^	GASTR	Nausea/ Nausea	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/4	2	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	22SEP2020	1/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	28SEP2020	5/2	2	Yes		NA	R (29SEP2020)	N/N
		GENRL	Pyrexia/ Fever	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
		MUSC	Myalgia/ Generalized Myalgias	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/3	1	Yes		NA/TC	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1055 10551168		GENRL	Chills/ Chills	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
		GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1055 10551169	3^	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1055 10551171	3^	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/4	2	Yes		NA/TC	R (05SEP2020)	N/N
		MUSC	Myalgia/ Generalized Myalgias	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
			Pyrexia/ Fever	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
		NERV	Headache/ Headache	2	25SEP2020	2/1	1	Yes		NA/TC	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551173	3 [^]	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	1/1	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		NERV	Dizziness/ Lightheaded	1	04SEP2020	2/2	2	Yes		NA	R (05SEP2020)	N/N
			Headache/ Headache	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1055 10551175	3 [^]	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/3	2	Yes		NA	R (06SEP2020)	N/N
		GENRL	Pyrexia/ Fever	1	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N
			Fatigue/ Fatigue	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ Injection site pain	2	23SEP2020	1/2	2	Yes		NA/TC	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1055 10551176	3 [^]	CARD	Arteriospasm coronary/ Coronary vasospasm	2	25SEP2020	3/2	3	No	O	NA	R (26SEP2020)	Y/N
16-55/ C459100	3 [^]	GENRL	Injection site pain/ Injection Site Tenderness	1	03SEP2020	1/5	2	Yes		NA/TC	R (07SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1055 10551177		GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	1/8	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1055 10551179	3^	MUSC	Myalgia/ Generalized Muscle Aches	1	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1055 10551184	3^	NERV	Headache/ Headache	2	24SEP2020	1/1	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1055 10551186	3^	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 1 1055 10551190	3^	GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/3	2	Yes		NA/TC	R (06SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100 1 1055 10551195	3^	GENRL	Fatigue/ Fatigue	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Dizziness/ Lightheaded	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/Y
16-55/ C459100 1 1055 10551198	3^	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1055 10551200	3^	GENRL	Chest discomfort/ Chest tightness	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
			Fatigue/ Fatigue	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	1	09SEP2020	2/3	1	Yes		NA/TC	R (11SEP2020)	N/N
		GENRL	Chills/ Chills	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
		MUSC	Myalgia/ Myalgias	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
		GENRL	Chest discomfort/ Chest tightness	2	01OCT2020	3/2	1	Yes		NA	R (02OCT2020)	N/N
		EAR	Vertigo/ Vertigo	2	23OCT2020	25/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1055 10551204	3^	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/6	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551207	3^	GENRL	Chills/ Chills	1	13SEP2020	5/1	2	Yes		NA	R (13SEP2020)	N/N
			Pyrexia/ Fever	1	13SEP2020	5/1	2	Yes		NA/TC	R (13SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	1	13SEP2020	5/1	2	Yes		NA	R (13SEP2020)	N/N
		MUSC	Costochondritis/ costochondritis	2	02OCT2020	3/4	2	Yes		NA/TC	R (05OCT2020)	N/N
		SKIN	Rash maculo-papular/ Maculopapular rash	1	20SEP2020	12/48	1	No	CD	NA/TC	R (06NOV2020)	N/N
		GENRL	Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
		MUSC	Myalgia/ Generalized Myalgias	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
		MUSC	Arthralgia/ Arthralgias	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
		NERV	Headache/ Headache	1	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1055 10551219		GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	01OCT2020	1/3	2	Yes		NA/TC	R (03OCT2020)	N/N
		GENRL	Chills/ Chills	2	02OCT2020	2/1	2	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Fatigue	2	02OCT2020	2/4	2	Yes		NA	R (05OCT2020)	N/N
			Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		MUSC	Arthralgia/ Generalized Joint aches	2	02OCT2020	2/2	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1055 10551221	3^	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1055 10551222	3^	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1055 10551223	3^	MUSC	Muscle fatigue/ Muscle fatigue	1	12SEP2020	2/11	1	Yes		NA	R (22SEP2020)	N/N
		GASTR	Gastrointestinal disorder/ Gastrointestinal frequency	1	13SEP2020	3/11	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551224	3^	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1055 10551225	3^	NERV	Hyperaesthesia/ Hyperaesthesia	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1055 10551226	3^	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
		MUSC	Myalgia/ Myalgias	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
		NERV	Headache/ Headache	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
		INJ&P	Facial bones fracture/ Fractured nose	2	26OCT2020	25/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1055 10551229	3^	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	1/5	2	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Malaise/ Malaise	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	06OCT2020	2/3	2	Yes		NA/TC	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1055 10551230	3^	MUSC	Malaise/ Malaise	2	06OCT2020	2/3	2	Yes		NA	R (08OCT2020)	N/N
			Arthralgia/ Generalized joint pain	2	06OCT2020	2/3	2	Yes		NA/TC	R (08OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		GENRL	Chills/ Chills	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1055 10551232	3^	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/ Injection site pain	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/4	2	Yes		NA	R (09OCT2020)	N/N
			Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		MUSC	Myalgia/ Generalized myalgias	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1055 10551233		MUSC	Myalgia/ Generalized myalgias	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1055 10551235	3^	GENRL	Pyrexia/ Fever	1	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	1	15SEP2020	1/6	2	Yes		NA	R (20SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ Fever	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
		MUSC	Myalgia/ Generalized myalgias	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
		GASTR	Nausea/ Nausea	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1055 10551237	3^	GENRL	Chills/ Chills	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
			Fatigue/ Fatigue	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ Injection site pain	1	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
			Pyrexia/ Fever	1	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ Fatigue	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
			Injection site pain/ Injection site pain	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1055 10551238	3^	GENRL	Injection site pain/ Injection Site Pain	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/Y
16-55/ C459100 1 1055 10551239	3^	GENRL	Pyrexia/ Fever	1	18SEP2020	2/3	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100 1 1055 10551240	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1056 10561013	3^	GENRL	Chills/ CHILLS	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N
16-55/ C459100 1 1056 10561016	3^	INJ&P	Contusion/ MULTIPLE CONTUSION	2	26SEP2020	18/34	2	No	O	NA/TC	R (29OCT2020)	N/N
			Road traffic accident/ CAR ACCIDENT	2	26SEP2020	18/1	2	No	O	NA/TC	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1056 10561022	3^	BLOOD	Lymphadenopathy/ SWOLLEN LEFT AXILLARY LYMPH NODES	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Injection site erythema/ INJECTION SITE ERYTHEMA	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
			Injection site pain/ PAIN AT INJECTION SITE	2	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C459100 1 1056 10561039	3^	GENRL	Pyrexia/ FEVER	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1056 10561058	3^	GENRL	Pyrexia/ FEVER	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1056 10561059	3^	GASTR	Diarrhoea/ DIARRHEA	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ LEFT ARM INJECTION SITE MUSCLE PAIN	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ FEVER	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1056 10561089	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE MUSCLE PAIN	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ FEVER	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1056 10561108	3^	GENRL	Injection site swelling/ INJECTION SITE SWELLING	1	04SEP2020	4/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1056 10561146	3^	GENRL	Pyrexia/ FEVER	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1056 10561177	3^	GENRL	Chills/ CHILLS	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
			Fatigue/ FATIGUE	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
			Injection site pain/ INJECTION SITE MUSCLE PAIN	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
			Pyrexia/ FEVER	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 1 1056 10561187	3^	GENRL	Injection site pain/ RIGHT ARM INJECTION SITE MUSCLE PAIN	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ TIREDNESS	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1056 10561213	3^	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
1 1056 10561219	3^	GENRL	Fatigue/ TIREDNESS	1	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N
1 1056 10561251	3^	GENRL	Pyrexia/ FEVER	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1056 10561252	3^	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1056 10561262	3^	GENRL	Chills/ CHILLS	1	01OCT2020	16/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1056 10561262	3^	GENRL	Pyrexia/ FEVER	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1056 10561277	3^	GENRL	Injection site pain/ MUSCLE PAIN (INJECTION SITE LEFT)	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
			Pyrexia/ FEVER	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1056 10561315	3^	RESP	Nasal congestion/ NASAL CONGESTION	1	30SEP2020	9/4	1	No	O	NA	R (03OCT2020)	N/N
		GENRL	Pyrexia/ FEVER	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1056 10561327	3^	GENRL	Chills/ CHILLS	1	27SEP2020	4/4	1	Yes		NA/TC	R (30SEP2020)	N/N
		MUSC	Arthralgia/ GENERALIZED JOINT PAIN	1	27SEP2020	4/4	1	Yes		NA/TC	R (30SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	27SEP2020	4/4	1	Yes		NA/TC	R (30SEP2020)	N/N
		GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1056 10561360	3^	GENRL	Pyrexia/ FEVER	2	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
		GENRL	Pyrexia/ FEVER	2	21OCT2020	3/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1056 10561375	3^	GENRL	Chills/ CHILLS	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
		MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1056 10561396	3^	NERV	Headache/ HEADACHE	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
		MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1056 10561442	3^	NERV	Headache/ HEADACHE	1	11OCT2020	7/2	1	Yes		NA	R (12OCT2020)	N/N
		GENRL	Chills/ CHILLS	1	12OCT2020	8/2	1	Yes		NA	R (13OCT2020)	N/N
		GENRL	Pyrexia/ FEVER	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C459100 1 1056 10561444	3^	GENRL	Pyrexia/ FEVER	1	09OCT2020	2/7	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	1	09OCT2020	2/8	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Pyrexia/ FEVER	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C459100 1 1056 10561453	3^	GENRL	Chills/ CHILLS	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1057 10571083	3^	MUSC	Pyrexia/ FEVER	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
			Myalgia/ GENERALIZED MUSCLE PAIN	2	29OCT2020	2/9	1	Yes		NA	R (06NOV2020)	N/N
		GASTR	Nausea/ NAUSEA	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		INV	Vomiting/ VOMITTING	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
			Blood pressure increased/ INCREASED BLOOD PRESSURE	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		NERV	Headache/ HEADACHE	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		GASTR	Vomiting/ VOMITTING	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		INV	Injection site pain/ PAIN AT INJECTION SITE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
			Blood pressure increased/ INCREASED BLOOD PRESSURE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
NERV	Headache/ HEADACHE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N		
16-55/ C459100	3^	RESP	Throat irritation/ THROAT IRRITATION	2	19SEP2020	4/1	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1057 10571122	3^	GASTR	Vomiting/ Vomiting	1	08SEP2020	8/2	1	No	O	NA	R (09SEP2020)	N/N
1 1057 10571132	3^	NEOPL	Uterine leiomyoma/ WORSENING OF UTERINE FIBROIDS	1	14SEP2020	14/6	2	No	O	NA/TCN	R (19SEP2020)	Y/N
1 1057 10571137	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
1 1057 10571165	3^	GASTR	Diarrhoea/ DIARRHEA	1	12SEP2020	3/2	1	Yes		NA	R (13SEP2020)	N/N
1 1057 10571239	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	2	15OCT2020	2/8	2	No	O	NA	R (22OCT2020)	N/N
1 1057 10571241	3^	GENRL	Injection site pain/ SORENESS INJECTION SITE LEFT ARM	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Pain/ BODY ACHES	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1057 10571246	3^	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	1	25SEP2020	1/6	2	Yes		NA	R (30SEP2020)	N/N
			Pain/ BODY ACHES	1	25SEP2020	1/6	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1057 10571263	3^	RESP	Nasal congestion/ Nasal Congestion	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1057 10571273	3^	GENRL	Injection site pruritus/ Itchiness on Left Arm at Injection Site	1	08OCT2020	2/5	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C459100 1 1057 10571278	3^	GENRL	Injection site pain/ Pain at Injection Site	1	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1066 10661019	3^	GENRL	Fatigue/ fatigue	1	18AUG2020	7/2	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C459100 1 1066 10661020	3^	GENRL	Fatigue/ fatigue	1	13AUG2020	2/2	1	Yes		NA	R (14AUG2020)	N/N
			Injection site pain/ pain at injection site	1	13AUG2020	2/3	1	Yes		NA	R (15AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1066 10661026	3^	GENRL	Fatigue/ fatigue	1	16AUG2020	4/2	1	Yes		NA	R (17AUG2020)	N/N
		NERV	Headache/ headache	1	16AUG2020	4/2	1	Yes		NA	R (17AUG2020)	N/N
		GENRL	Fatigue/ fatigue	1	18AUG2020	6/2	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C459100 1 1066 10661027	3^	GENRL	Fatigue/ fatigue	1	16AUG2020	4/5	2	Yes		NA	R (20AUG2020)	N/N
		GENRL	Chills/ chills	1	17AUG2020	5/4	2	Yes		NA	R (20AUG2020)	N/N
		NERV	Headache/ headache	1	17AUG2020	5/4	2	Yes		NA/TC	R (20AUG2020)	N/N
16-55/ C459100 1 1066 10661095	3^	MUSC	Back pain/ lower back pain	2	06OCT2020	23/3	2	No	O	NA	R (08OCT2020)	N/N
16-55/ C459100 1 1066 10661106	3^	GENRL	Pain/ body aches	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 1 1066 10661182	3^	GENRL	Fatigue/ fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pain/ body aches	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1066 10661192	3^	IN FEC	Diverticulitis/ diverticulitis	2	07NOV2020	44/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1066 10661226	3^	VASC	Hot flush/ hot flashes	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1066 10661235	3^	GASTR	Diarrhoea/ diarrhea	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		GENRL	Pain/ body aches	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1066 10661264	3^	GENRL	Chills/ chills	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100	3^	IN FEC	Herpes zoster/ Herpes zoster	2	24OCT2020	16/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1066 10661275	3^	GASTR	Nausea/ nausea	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
1 1066 10661279		GENRL	Fatigue/ fatigue	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
			Pain/ body aches	2	13OCT2020	1/4	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1066 10661294	3^	GENRL	Pain/ body aches	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
			Pyrexia/ fever	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1066 10661308	3^	GENRL	Injection site pain/ pain at injection site	1	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1066 10661315	3^	GENRL	Injection site pain/ pain at injection site	1	06OCT2020	2/4	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ pain at injection site	1	19AUG2020	2/4	2	Yes		NA/TC/TCN	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1068 10681002		NERV	Dizziness/ lightheadedness	1	19AUG2020	2/4	1	Yes		NA/TC/TCN	R (22AUG2020)	N/N
			Headache/ Headache	1	19AUG2020	2/4	2	Yes		NA/TC/TCN	R (22AUG2020)	N/N
		GASTR	Nausea/ Nausea	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Chills/ Chills	2	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
		MUSC	Arthralgia/ Joint Aches	2	10SEP2020	2/2	2	Yes		NA/TC/TCN	R (11SEP2020)	N/N
			Myalgia/ Muscle Aches	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1068 10681021	3^	GENRL	Fatigue/ Fatigue	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
			Pyrexia/ Fever	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
		GENRL	Chills/ chills	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ fever	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1068 10681024	3^	GENRL	Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA/TC/TCN	R (11SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1068 10681026	3^	GENRL	Injection site pain/ Injection Site pain	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
		MUSC	Myalgia/ Generalized myalgia	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C459100 1 1068 10681027	3^	GENRL	Injection site pain/ Pain at the injection site	1	21AUG2020	1/2	1	Yes		NA/TC	R (22AUG2020)	N/N
		NERV	Headache/ Headache	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	22/4	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1068 10681035		MUSC	Arthralgia/ Joint Aches	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N
			Myalgia/ Muscle Aches	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1068 10681037	3^	RESP	Dyspnoea/ shortness of breath	1	31AUG2020	8/17	2	No	O	NA	R (16SEP2020)	N/N
16-55/ C459100 1 1068 10681042	3^	GASTR	Nausea/ Nausea	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		GENRL	Chills/ Chills	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ Fever	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1068 10681046	3^	GENRL	Chills/ Chills	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ Injection Site Pain	1	16SEP2020	22/1	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1068 10681052	3^	MUSC	Pyrexia/ Fever	1	16SEP2020	22/3	1	Yes		NA	R (18SEP2020)	N/N
			Myalgia/ Muscle Aches	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		EYE	Eye pruritus/ Right Eye Itching	2	17OCT2020	32/2	1	No	O	NA	R (18OCT2020)	N/N
		MUSC	Tendonitis/ Tendonitis of the right forearm	1	15SEP2020	20/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1068 10681053	3^	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		MUSC	Joint range of motion decreased/ Decreased left shoulder mobility	1	27AUG2020	1/3	2	Yes		NA	R (29AUG2020)	N/N
		GENRL	Injection site pain/ injection Site Pain	1	05SEP2020	10/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 1 1068 10681058	3^	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/1	1	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Pain/ Body aches	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1068 10681060	3^	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/3	2	Yes		NA/TC/TCN	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1068 10681064	3^	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	2	18SEP2020	2/2	2	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Pain/ Body aches	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1068 10681066	3^	GASTR	Nausea/ Nausea	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1068 10681077	3^	BLOOD	Lymphadenopathy/ Left swollen cervical lymph node	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
		GASTR	Gingival swelling/ Gum Swelling	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1068 10681077	3^	MUSC	Myalgia/ Muscle Aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ headache	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1068 10681086	3^	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Pain/ body aches	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1068 10681098	3^	GENRL	Injection site pain/ Pain at injection site	1	03SEP2020	1/5	2	Yes		NA	R (07SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	04SEP2020	2/1	1	Yes		NA	R (04SEP2020)	N/N
			Pain/ Body Aches	1	04SEP2020	2/1	2	Yes		NA/TC	R (04SEP2020)	N/N
16-55/ C459100 1 1068 10681100	3^	GENRL	Fatigue/ Fatigue	1	06SEP2020	4/9	1	Yes		NA/TC	R (14SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N
		NERV	Headache/ headache	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C459100 1 1068 10681106	3^	GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
			Injection site pain/ injection site pain	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1068 10681109	3^	GENRL	Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
			GASTR	Nausea/ Nausea	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
			NERV	Headache/ Headache	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
			GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/3	2	Yes		NA/TC	R (06SEP2020)	N/N
			GENRL	Injection site pain/ Injection site pain	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 1 1068 10681110	3^	UNC	Chills/ Chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N	
			Pyrexia/ Fever	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N	
16-55/ C459100 1 1068 10681113	3^	SKIN	LEFT FOREARM HIVES@@/ Left forearm hives	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N	
			Rash/ Rash on arm	1	11SEP2020	4/3	1	Yes		NA	R (13SEP2020)	N/N	
			GASTR	Nausea/ nausea	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
			NERV	Presyncope/ near syncope	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1068 10681119	3^	GENRL	Chills/ chills	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N	
			Fatigue/ fatigue	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N	
			Pyrexia/ fever	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N	
			NERV	Headache/ headache	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1068 10681121	3^	MUSC	Myalgia/ muscle aches in back	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N	
			Pain in extremity/ pain in left arm	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N	
			NERV	Headache/ headache	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
			MUSC	Musculoskeletal chest pain/ chest tightness consistent with skeletal pain	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C459100 1 1071 10711004	3^	RESP	Oropharyngeal pain/ SORE THROAT	2	23SEP2020	21/1	1	No	O	NA	R (23SEP2020)	N/N	
16-55/ C459100 1 1071 10711019	3^	NERV	Headache/ HEADACHE	2	07SEP2020	6/4	2	Yes		NA	R (10SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1071 10711027	3^	PSYCH	Irritability/ IRRITABILITY	1	12AUG2020	1/8	1	No	O	NA	R (19AUG2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	13AUG2020	2/7	1	No	O	NA	R (19AUG2020)	N/N
16-55/ C459100 1 1071 10711039	3^	GENRL	Fatigue/ FATIGUE	2	09SEP2020	6/13	2	Yes		NA	R (21SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	09SEP2020	6/13	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1071 10711056	3^	MUSC	Arthralgia/ RIGHT SHOULDER PAIN	2	17SEP2020	10/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1071 10711061	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
			Pain/ GENERALIZED BODY PAIN	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1071 10711065	3^	NERV	Headache/ HEADACHE	2	15SEP2020	7/2	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11071 10711080	3^	MUSC	Neck pain/ NECK PAIN	1	04SEP2020	14/2	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C459100 11071 10711083	3^	GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
			Vomiting/ VOMITTING	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
		GENRL	Chills/ CHILLS	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
		MUSC	Back pain/ WORSENING OF BACK PAIN	1	28AUG2020	5/3	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 11071 10711119	3^	MUSC	Myalgia/ GENERAL MUSCLE PAIN	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 11071 10711125	3^	GENRL	Chills/ CHILLS	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
			Pain/ GENERAL BODY ACHES	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1071 10711133		GENRL	Fatigue/ FATIGUE	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
			Pyrexia/ FEVER AFTER INJECTION	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C459100 1 1071 10711138	3^	GENRL	Pyrexia/ FEVER AFTER INJECTION	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		SKIN	Night sweats/ NIGHT SWEATS	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1071 10711151	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1071 10711153	3^	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	01OCT2020	3/4	1	Yes		NA	R (04OCT2020)	N/N
			Injection site pain/ PAIN AT INJECTION SITE	2	01OCT2020	3/4	1	Yes		NA	R (04OCT2020)	N/N
			Injection site swelling/ SWELLING AT INJECTION SITE	2	01OCT2020	3/4	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1071 10711159	3^	GENRL	Fatigue/ FATIGUE	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ MUSCLE ACHES	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1071 10711160	3^	NEOPL	Lipoma/ BENIGN LIPOMA LEFT ARM	1	28SEP2020	18/5	1	No	O	NA	R (02OCT2020)	N/N
16-55/ C459100 1 1071 10711167	3^	INJ&P	Contusion/ BRUISING LEFT ARM	1	18SEP2020	4/13	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1071 10711171	3^	BLOOD	Lymphadenopathy/ SWOLLEN LYMPH NODE UNDER LEFT ARMPIT	2	07OCT2020	3/6	2	Yes		NA	R (12OCT2020)	N/N
16-55/ C459100 1 1071 10711176	3^	GENRL	Injection site pain/ MUSCLE PAIN AT INJECTION SITE	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1071 10711183	3^	NERV	Headache/ HEADACHE	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1071 10711193	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/Y
16-55/ C459100 1 1071 10711199	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1071 10711200	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1071 10711206	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	28SEP2020	3/1	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C459100 1 1071 10711213	3^	GENRL	Pyrexia/ FEVER	1	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1071 10711215	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1072 10721001	3^	GASTR	Nausea/ Nausea	1	22AUG2020	6/2	1	No	O	NA	R (23AUG2020)	N/N
		GENRL	Malaise/ General Malaise	1	22AUG2020	6/2	1	No	O	NA/TC	R (23AUG2020)	N/N
16-55/ C459100 1 1072 10721035	3^	GENRL	Injection site pain/ Injection Site Pain Left Arm	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N
16-55/ C459100 1 1077 10771004	3^	MUSC	Pain in extremity/ BILATERAL HAND PAIN	2	07SEP2020	8/6	1	No	O	NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1077 10771007	3^	INFEC	Diverticulitis/ FLARE OF DIVERTICULITIS	2	02OCT2020	33/6	1	No	O	NA/TC	R (07OCT2020)	N/N
		GENRL	Pyrexia/ FEVER OF 101.0	1	17AUG2020	8/2	1	Yes		NA/TC	R (18AUG2020)	N/N
16-55/ C459100 1 1077 10771013	3^	RESP	Sinus congestion/ SINUS CONGESTION	1	17AUG2020	8/3	2	Yes		NA	R (19AUG2020)	N/N
		NERV	Dizziness/ DIZZINESS	2	02OCT2020	29/1	2	No	O	NA	R (02OCT2020)	N/N
		PSYCH	Depression/ WORSENING DEPRESSION	1	21AUG2020	12/C	2	No	O	NA/TC	N	N/N
		INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2	26SEP2020	27/47	1	No	O	NA/TC	R (11NOV2020)	N/N
16-55/ C459100 1 1077 10771038	3^	VASC	Haematoma/ HEMATOMA LEFT ARM	2	01OCT2020	30/18	2	No	O	NA	R (18OCT2020)	N/N
16-55/ C459100 1 1077 10771044	3^	INFEC	Herpes zoster/ ZOSTER WITHOUT COMPLICATIONS	2	26SEP2020	19/12	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1077 10771045	3^	METAB	Type 2 diabetes mellitus/ TYPE II DIABETES	2	09OCT2020	30/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1077 10771054	3^	INFEC	Nasopharyngitis/ COMMON COLD	1	29AUG2020	13/7	1	No	O	NA	R (04SEP2020)	N/N
		INFEC	Urinary tract infection/ URINARY TRACT INFECTION	1	06SEP2020	21/11	2	No	O	NA/TC	R (16SEP2020)	N/N
		REPRO	Polycystic ovaries/ POLYCYSTIC OVARIAN SYNDROME	2	01OCT2020	23/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1077 10771058	3^	GASTR	Nausea/ NAUSEA	1	21AUG2020	5/15	2	No	CD	NA	R (04SEP2020)	N/N
			Vomiting/ INTERMITTENT VOMITING	1	21AUG2020	5/15	2	No	CD	NA	R (04SEP2020)	N/N
16-55/ C459100 1 1077 10771089	3^	NERV	Dizziness/ DIZZINESS	2	12OCT2020	29/1	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C459100 1 1077 10771126	3^	PSYCH	Anxiety/ WORSENING ANXIETY	1	09SEP2020	15/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1077 10771169	3^	METAB	Hyperlipidaemia/ HYPERLIPIDEMIA	2	07OCT2020	17/C	1	No	O	NA/TC	N	N/N
16-55/ C459100	3^	PSYCH	Anxiety/ WORSENING ANXIETY	2	02OCT2020	10/C	1	No	O	NA/TC	N	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1077 10771171	3^	SKIN	Dermatitis contact/ POISON IVY RASH	2	10OCT2020	17/C	1	No	O	NA/TC	N	N/N
1 1077 10771178	3^	METAB	Hyperlipidaemia/ HYPERLIPIDEMIA	2	22OCT2020	28/C	1	No	O	NA/TC	N	N/N
1 1077 10771184	3^	SKIN	Urticaria/ URTICARIA	1	08SEP2020	6/2	2	No	O	NA/TC	R (09SEP2020)	N/N
1 1077 10771189		INFEC	Lyme disease/ LYME'S DISEASE	2	19OCT2020	28/C	1	No	O	NA/TC	N	N/N
1 1077 10771238	3^	INFEC	Ear infection/ LEFT EAR INFECTION	1	02OCT2020	15/10	1	No	O	NA/TC	R (11OCT2020)	N/N
1 1079 10791004	2^	NEOPL	Adenocarcinoma gastric/ INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	1	20AUG2020	23/C	3	No	O	P/W	N	Y/N
1 1079 10791010	2^	RESP	Productive cough/ Wet Cough	1	30JUL2020	1/1	1	No	O	NA	R (30JUL2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Rhinorrhoea/ Runny Nose	1	30JUL2020	1/1	1	No	O	NA	R (30JUL2020)	N/N
16-55/ C459100 1 1079 10791143	3^	SKIN	Dermatitis contact/ Poison Ivy RASH (Arms and Legs)	1	08SEP2020	22/11	2	No	O	NA/TC/TCN	R (18SEP2020)	N/N
16-55/ C459100 1 1079 10791245	3^	GENRL	Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	2	05OCT2020	13/3	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C459100 1 1080 10801002	3^	GASTR	Gastric ulcer haemorrhage/ Bleeding Ulcers (Stomach)	1	11AUG2020	2/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1080 10801045	3^	GASTR	Diarrhoea/ diarrhea	2	08SEP2020	1/1	1	Yes		NA/TC	R (08SEP2020)	N/N
			Nausea/ Nausea	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
		MUSC	Pain in extremity/ Soreness - Right Arm	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N
		SKIN	Erythema/ Redness in Right arm	2	09SEP2020	2/5	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100 1 1080 10801051	3^	GENRL	Chest discomfort/ Chest Pressure	1	22AUG2020	6/2	2	No	O	NA/TC	R (23AUG2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1080 10801057	3^	GENRL	Injection site erythema/ Redness at injection site	2	09SEP2020	1/6	1	Yes		NA	R (14SEP2020)	N/N
			Injection site pain/ Soreness at injection site	2	09SEP2020	1/7	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1080 10801068	3^	GASTR	Nausea/ Nausea	2	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Chills/ Chills	2	10SEP2020	1/6	2	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	1/6	2	Yes		NA	R (15SEP2020)	N/N
		RESP	Cough/ Cough	2	12SEP2020	3/4	1	No	O	NA	R (15SEP2020)	N/N
		GASTR	Noninfective gingivitis/ Inflamed Gums	2	14SEP2020	5/2	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C459100 1 1080 10801096	3^	GENRL	Chills/ Chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1080 10801109	3^	UNC	FEVER@@/ Fever	2	19SEP2020	2/2	1	Yes			R (20SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Soreness at injection site	1	28AUG2020	1/4	2	Yes		NA	R (31AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1080 10801117	3^	GASTR	Diarrhoea/ Diarrhea	2	01OCT2020	7/1	1	No	O	NA	R (01OCT2020)	N/N
1 1080 10801159	3^	SKIN	Dermatitis atopic/ Atopic Dermatitis	1	27AUG2020	16/C	2	No	O	NA/TC	RG	N/N
1 1081 10811023	3^	INFEC	Appendicitis/ Appendicitis	1	21AUG2020	9/3	3	No	O	NA/TC/TCN	R (23AUG2020)	Y/N
1 1081 10811036	3^	METAB	Hyperglycaemia/ Hyperglycemic episode	2	17SEP2020	9/2	3	No	O	NA	R (18SEP2020)	Y/N
1 1081 10811046	3^	RESP	Paranasal sinus discomfort/ sinus nasal pressure	2	03OCT2020	24/2	1	No	O	NA/TC	R (04OCT2020)	N/N
1 1081 10811075	3^	GENRL	Fatigue/ fatigue	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
1 1081 10811085		NERV	Headache/ headache	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1081 10811096	3^	RENAL	Nephrolithiasis/ Kidney Stone	1	06SEP2020	13/1	2	No	O	NA	R (06SEP2020)	N/N
16-55/ C459100 1 1081 10811119	3^	NERV	Syncope/ Episode of Syncope	2	29SEP2020	15/1	1	No	O	NA	R (29SEP2020)	N/N
16-55/ C459100 1 1081 10811133	3^	INJ&P	Foreign body in eye/ Foreign body eye	2	04OCT2020	13/1	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 1081 10811134	3^	NERV	Headache/ Headache	2	12OCT2020	21/2	1	No	O	NA	R (13OCT2020)	N/N
		RESP	Oropharyngeal pain/ Sore throat	2	12OCT2020	21/2	1	No	O	NA	R (13OCT2020)	N/N
16-55/ C459100 1 1081 10811135	3^	CARD	Myocardial infarction/ Myocardial Infarction	2	21OCT2020	30/C	4	No	O	NA/TC/TCN	RG	Y/N
		METAB	Type 2 diabetes mellitus/ New Onset Type II Diabetes Mellitus	2	21OCT2020	30/C	3	No	O	NA/TC	RG	Y/N
16-55/ C459100 1 1081 10811194	3^	GENRL	Death/ Death	2	01NOV2020	34/1	4	No	O	NA/W	F (01NOV2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1081 10811196	3^	INFEC	Hordeolum/ left eye lower lid sty	2	03OCT2020	3/11	1	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C459100 1 1081 10811198	3^	GENRL	Chills/ Chills	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
			Pain/ Body Aches	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ Fever	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1081 10811206	3^	GENRL	Pyrexia/ Fever	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ Headache	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1082 10821163	3^	CARD	Ventricular tachycardia/ paroxysmal ventricular tachycardia	2	06NOV2020	26/2	2	No	O	NA	R (07NOV2020)	N/N
16-55/ C459100 1 1082 10821195	3^	INFEC	Tooth abscess/ dentoalveolar abscess tooth #15	1	20OCT2020	12/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1083 10831001	2^	INJ&P	Fall/ Fall	2	26AUG2020	6/1	2	No	O	NA	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Fibula fracture/ Fibula fracture	2	26AUG2020	6/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1083 10831004	2^	SKIN	Hangnail/ Hang Nail	1	31JUL2020	3/8	1	No	O	NA/TC	R (07AUG2020)	N/N
16-55/ C459100 1 1083 10831013	3^	INV	Heart rate increased/ Rapid Heart Beat	1	31JUL2020	2/1	1	No	O	NA	R (31JUL2020)	N/N
		MUSC	Scoliosis/ Increased Back Pain secondary to Scoliosis	2	06OCT2020	48/11	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1083 10831029	3^	CARD	Atrial fibrillation/ Paroxysmal Atrial fibrillation with rapid ventricular response	1	23AUG2020	20/17	3	No	O	P/TC/TCN	R (08SEP2020)	Y/N
		CARD	Left ventricular hypertrophy/ Left Ventricular Hypertrophy	1	24AUG2020	21/C	1	No	O	NA/TC	N	N/N
		VASC	Hypertension/ Hypertension	1	24AUG2020	21/C	1	No	O	NA/TC	N	N/N
		INJ&P	Skin laceration/ Laceration-Left Index Finger	1	01SEP2020	29/15	2	No	O	NA/TCN	R (15SEP2020)	N/N
		CARD	Atrial flutter/ Atrial Flutter	1	02SEP2020	30/7	3	No	O	NA/TC/TCN	R (08SEP2020)	N/N
		CARD	Myocardial infarction/ Prior Septual Myocardial Infarction	1	08SEP2020	36/1	1	No	O	NA	R (08SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		CARD	Left atrial enlargement/ Left Atrial Enlargement	1	09SEP2020	37/C	1	No	O	NA	N	N/N
			Mitral valve incompetence/ Mitral Regurgitation	1	09SEP2020	37/C	1	No	O	NA	RG	N/N
			Mitral valve prolapse/ Bileaflet mitral valve prolapse	1	09SEP2020	37/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1083 10831040	3^	PSYCH	Anxiety/ Situational Anxiety	2	27AUG2020	3/C	1	No	O	NA/TC	N	N/N
		NEOPL	Uterine leiomyoma/ Worsening of Uterine Fibroids	2	16SEP2020	23/C	1	No	O	NA	N	N/N
			16-55/ C459100 1 1083 10831057	3^	INFEC	Diverticulitis/ Diverticulitis Flare	1	09AUG2020	5/11	2	No	O
16-55/ C459100 1 1083 10831060	3^	GASTR	Abdominal pain/ Worsening of Abdominal Pain	1	14AUG2020	9/11	4	No	O	NA/TC	R (24AUG2020)	N/N
			Diverticular perforation/ Ruptured diverticulum	1	14AUG2020	9/11	4	No	O	P/TC/TCN	R (24AUG2020)	Y/N
		INJ&P	Postoperative ileus/ Post Operative Ileus	1	18AUG2020	13/6	2	No	O	NA/TC	R (23AUG2020)	N/N
		GASTR	Small intestinal obstruction/ Small Bowel Obstruction	1	20AUG2020	15/1	3	No	O	NA/TC/TCN	R (20AUG2020)	N/N
		INFEC	Cellulitis/ Phlegmon Formation	1	20AUG2020	15/1	3	No	O	NA/TC/TCN	R (20AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Diverticulitis/ Diverticulitis	1	20AUG2020	15/C	4	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 1 1083 10831074	3^	GASTR	Diarrhoea/ Diarrhea	1	16AUG2020	7/46	2	No	O	NA/TC	R (30SEP2020)	N/N
		GASTR	Toothache/ Toothache	1	18AUG2020	9/32	2	No	O	NA/TC	R (18SEP2020)	N/N
		IMMUN	Drug hypersensitivity/ Oral Penicillin Reaction	1	25AUG2020	16/3	1	No	O	NA	R (27AUG2020)	N/N
16-55/ C459100 1 1083 10831084	3^	INJ&P	Meniscus injury/ Bruised Right Meniscus	1	17AUG2020	7/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1083 10831086	3^	MUSC	Arthralgia/ Wrist Pain	1	29AUG2020	19/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1083 10831098	3^	MUSC	Neck pain/ Neck Pain	1	17AUG2020	5/4	2	No	O	NA/TC	R (20AUG2020)	N/N
		NERV	Headache/ Headache	1	18AUG2020	6/3	2	No	O	NA/TC	R (20AUG2020)	N/N
16-55/ C459100 1 1083 10831101	3^	INV	Body temperature increased/ Elevated Temperature	1	14AUG2020	2/1	1	Yes		NA	R (14AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GASTR	Abdominal pain upper/ Intermittent Pain-Left Upper Quadrant	1	19AUG2020	7/C	2	No	O	NA/TC	RG	N/N
		INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	1	19AUG2020	7/42	2	No	O	NA/TC	R (29SEP2020)	N/N
		GASTR	Constipation/ Constipation	2	29SEP2020	29/C	1	No	O	NA	RG	N/N
			Gastrointestinal disorder/ Gastrointestinal Issue	2	29SEP2020	29/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1083 10831113	3^	NERV	Syncope/ Syncope*		18AUG2020	1/1	1	No	O	NA	R (18AUG2020)	N/N
16-55/ C459100 1 1083 10831119	3^	GASTR	Toothache/ Toothache -Lower Left Side Wisdom tooth	1	04SEP2020	18/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1083 10831124	3^	VASC	Varicose vein/ pain secondary to varicose vein in left thigh	2	06OCT2020	28/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1083 10831142	3^	PSYCH	Panic attack/ Worsening of Panic Attacks	1	31AUG2020	8/C	2	No	O	NA/TC	N	N/N
		SURG	Dental implantation/ Upper Dental Implant Surgery- Cosmetic	2	01OCT2020	18/1	1	No	O	NA/TC	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1083 10831152	3^	SKIN	Dermatitis acneiform/ Acneiform Rash- Torso,Thighs,Upper Arms	1	03SEP2020	10/38	1	No	O	NA/TC	R (10OCT2020)	N/N
		SKIN	Eczema/ eczema	1	01OCT2020	38/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1083 10831162	3^	GASTR	Abdominal pain upper/ Worsening of Right Upper Quadrant Pain	1	14SEP2020	20/C	1	No	O	NA	RG	N/N
		GASTR	Diarrhoea/ Diarrhea-Intermittent	2	18SEP2020	3/C	2	No	O	NA	RG	N/N
			Nausea/ Intermittent Nausea	2	18SEP2020	3/C	2	No	O	NA	RG	N/N
			Vomiting/ Vomiting	2	18SEP2020	3/3	2	No	O	NA	R (20SEP2020)	N/N
16-55/ C459100 1 1083 10831179	3^	GASTR	Diarrhoea/ Diarrhea-Intermittent	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
		MUSC	Back pain/ Worsening of Lumbar Back Pain	1	18SEP2020	19/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1083 10831181	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	01SEP2020	2/7	1	No	O	NA/TC	R (07SEP2020)	N/N
		RESP	Oropharyngeal pain/ Sore Throat-Intermittent	2	03OCT2020	13/2	1	No	O	NA	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1083 10831194	3^	CARD	Atrial fibrillation/ New Onset Atrial Fibrillation with rapid ventricular response	2	26OCT2020	34/C	2	No	O	NA/TC	RG	Y/N
			Mitral valve incompetence/ Trivial Mitral Regurgitation	2	26OCT2020	34/C	1	No	O	NA/TC	N	N/N
			Palpitations/ Heart Palpitations	2	26OCT2020	34/3	2	No	O	NA/TC	R (28OCT2020)	N/N
			GENRL Chest pain/ Chest Pain	2	26OCT2020	34/3	2	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C459100 1 1083 10831197	3^	BLOOD	Lymphadenitis/ Inflamed lymph nodes left breast	1	22SEP2020	19/C	1	No	O	NA	N	N/N
			INV	Mammogram abnormal/ Abnormal breast tissue on mammogram-left breast	1	22SEP2020	19/C	1	No	O	NA	N
		GENRL	Fatigue/ Fatigue	1	22OCT2020	49/2	1	Yes		NA	R (23OCT2020)	N/N
			Pyrexia/ Low Grade Temperature	1	22OCT2020	49/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1083 10831205	3^	RENAL	Pollakiuria/ Urinary Frequency	1	29SEP2020	21/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1083 10831268	3^	MUSC	Arthralgia/ Knee Pain-Right	2	02NOV2020	19/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1084 10841004	3^	SKIN	Rash/ rash all over body	1	14AUG2020	8/13	2	No	O	NA/TC	R (26AUG2020)	N/N
16-55/ C459100 1 1084 10841056	3^	GENRL	Fatigue/ Fatigue	2	26AUG2020	1/8	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 1 1084 10841058	3^	INFEC	Eye infection/ Right Eye Infection	2	29AUG2020	4/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1084 10841062	3^	INJ&P	Fall/ Fall	1	28AUG2020	22/1	1	No	O	NA	R (28AUG2020)	N/N
		MUSC	Arthralgia/ BILATERAL ANKLE PAIN	1	28AUG2020	22/30	2	No	O	NA	R (26SEP2020)	N/N
16-55/ C459100 1 1084 10841090	3^	INFEC	Tooth infection/ Left Upper Tooth Infection	2	28SEP2020	32/15	1	No	O	NA/TC	R (12OCT2020)	N/N
16-55/ C459100 1 1084 10841102	3^	MUSC	Osteoarthritis/ OSTEO ARTHRITIS	2	15SEP2020	16/C	1	No	O	NA	N	N/N
		NERV	Radiculopathy/ radiculopathy (femoral nerve)	2	15SEP2020	16/C	2	No	O	NA	N	N/N
16-55/ C459100	3^	INFEC	Sinusitis/ Sinusitis	2	28SEP2020	29/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1084 10841107 16-55/ C459100 1 1084 10841117	3^	INFEC	Cellulitis/ Cellulitis FRONT OF ABDOMEN	1	24AUG2020	15/3	2	No	O	NA	R (26AUG2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	13SEP2020	14/7	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1084 10841118	3^	INV	Weight decreased/ Weight-Loss	2	01SEP2020	5/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1084 10841121	3^	NERV	Ageusia/ LOSS OF TASTE	2	05SEP2020	2/7	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1084 10841136	3^	MUSC	Pain in jaw/ Right Jaw Pain	1	12AUG2020	1/2	2	Yes		NA	R (13AUG2020)	N/N
16-55/ C459100 1 1084 10841209	3^	INFEC	Pharyngitis streptococcal/ Strep Throat	2	16SEP2020	8/8	2	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1084 10841228	3^	GASTR	Diarrhoea/ Diarrhea	1	11SEP2020	24/4	1	No	O	NA/TC	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1084 10841269	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	2	29SEP2020	19/9	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1084 10841283	3^	MUSC	Pain in extremity/ right hand and foot pain	2	23OCT2020	29/4	2	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C459100 1 1084 10841294	3^	INJ&P	Ligament sprain/ Left Ankle Sprain	1	04SEP2020	10/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1084 10841301	3^	INJ&P	Ligament sprain/ Right Ankle Sprain	2	14OCT2020	29/C	2	No	O	NA	N	N/N
16-55/ C459100 1 1084 10841306	3^	NERV	Headache/ Headache in Frontal Lobe	2	12OCT2020	27/1	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C459100 1 1084 10841307	3^	GENRL	Peripheral swelling/ Bilateral Leg Swelling	1	29AUG2020	4/8	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C459100 1 1084 10841309	3^	NERV	Headache/ Headache	1	29AUG2020	2/1	1	No	O	NA	R (29AUG2020)	N/N
16-55/ C459100	3^	RESP	Cough/ Increased Cough	1	03SEP2020	7/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1084 10841312	3^	MUSC	Back pain/ Back pain	2	15OCT2020	28/2	1	No	O	NA	R (16OCT2020)	N/N
1 1084 10841315	3^	INFEC	Sinusitis/ Sinus Infection	1	01SEP2020	5/23	2	No	O	NA/TC	R (23SEP2020)	N/N
1 1084 10841316	3^	INFEC	Cellulitis/ Cellulitis in Left leg	1	08SEP2020	12/9	2	No	O	NA/TC/TCN	R (16SEP2020)	Y/N
1 1084 10841317	3^	RESP	Nasal congestion/ Worsening of Nasal Congestion	2	22SEP2020	2/21	1	No	O	NA	R (12OCT2020)	N/N
1 1084 10841327	3^	NERV	Parosmia/ olfactory hallucinations (phantosmia)	1	12SEP2020	2/35	1	No	O	NA	R (16OCT2020)	N/N
1 1084 10841376	3^	GASTR	Gastrooesophageal reflux disease/ Gerd	1	17SEP2020	4/C	2	No	O	NA/TC	N	N/N
1 1084 10841391	3^	RENAL	Haematuria/ haematuria	2	08OCT2020	2/C	1	No	O	NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1084 10841404	3^	INFEC	Ear infection/ left ear infection	1	01OCT2020	18/4	2	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 1084 10841422	3^	INJ&P	Ligament rupture/ Torn Ligament in Right Arm	1	07OCT2020	20/C	2	No	O	NA	N	N/N
16-55/ C459100 1 1084 10841428	3^	INJ&P	Arthropod sting/ Wasp Sting on right forearm	1	25SEP2020	8/2	1	No	O	NA/TC	R (26SEP2020)	N/N
16-55/ C459100 1 1084 10841429	3^	MUSC	Back pain/ WORSERING BACK PAIN	2	12NOV2020	30/C	1	No	O	NA/TC/TCN	N	N/N
16-55/ C459100 1 1084 10841449	3^	GENRL	Injection site pain/ injection site tenderness left arm	2	15OCT2020	2/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1084 10841454	3^	GASTR	Nausea/ Post dose Nausea	2	16OCT2020	1/1	1	No	O	NA	R (16OCT2020)	N/Y
		INFEC	Bronchitis/ Bronchitis	2	13NOV2020	29/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1085 10851142	3^	GENRL	Fatigue/ FATIGUE	2	21SEP2020	6/2	1	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1085 10851225	3^	GENRL	Pyrexia/ low grade fever	2	21SEP2020	6/2	1	Yes		NA/TC	R (22SEP2020)	N/N	
			MUSC	Myalgia/ MUSCLE ACHES	2	21SEP2020	6/2	1	Yes		NA	R (22SEP2020)	N/N
				Injection site pain/ Injection Site Pain	2	26SEP2020	3/2	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1085 10851248	3^	GENRL	Chills/ Chills	2	22SEP2020	2/6	1	Yes		NA	R (27SEP2020)	N/N	
16-55/ C459100 1 1085 10851250	3^	GASTR	Nausea/ Nausea	2	26SEP2020	6/2	1	Yes		NA	R (27SEP2020)	N/N	
		INFEC	Conjunctivitis/ conjunctivitis	1	16SEP2020	14/C	1	No	O	NA/TC	RG	N/N	
16-55/ C459100 1 1085 10851253	3^	GASTR	Diarrhoea/ Diarrhea	2	28OCT2020	35/1	1	No	CND	NA	R (28OCT2020)	N/N	
16-55/ C459100 1 1085 10851280	3^	GASTR	Diarrhoea/ Diarrhea	2	05NOV2020	43/1	1	No	CND	NA	R (05NOV2020)	N/N	
		GENRL	Chills/ CHILLS	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pain/ BODY ACHES	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1085 10851304	3^	GENRL	Pyrexia/ Fever	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1085 10851337	3^	GENRL	Chills/ Chills	2	08OCT2020	1/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1085 10851361	3^	GENRL	Injection site pain/ Injection site tenderness	1	10OCT2020	6/4	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1087 10871045	3^	IMMUN	Food allergy/ Egg White/Yolk Allergy - Allergy Test Finding	1	28AUG2020	19/C	1	No	O	NA	N	N/N
			Food allergy/ Kidney Bean Allergy - Allergy Test Findings	1	28AUG2020	19/C	1	No	O	NA	N	N/N
			Milk allergy/ Dairy Allergy - Allergy Test Findings	1	28AUG2020	19/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1087 10871046	3^	GASTR	Toothache/ TOOTH ACHE	2	02SEP2020	3/27	2	No	O	NA/TC/TCN	R (28SEP2020)	N/N
16-55/ C459100	3^	CARD	Tachycardia/ TACHYCARDIA	1	24SEP2020	39/7	2	No	O	NA/TC	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1087 10871089	3^	INFEC	Cellulitis/ CELLULITIS LEFT KNEE	1	03SEP2020	17/11	2	No	O	NA/TC	R (13SEP2020)	N/N
1 1087 10871094	3^	RESP	Nasal congestion/ NASAL CONGESTION	1	22AUG2020	5/2	1	No	O	NA	R (23AUG2020)	N/N
1 1087 10871109	3^	IMMUN	Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	2	27SEP2020	19/8	1	No	O	NA/TC	R (04OCT2020)	N/N
		GASTR	Nausea/ NAUSEA	2	08OCT2020	30/2	1	No	O	NA	R (09OCT2020)	N/N
			Vomiting/ VOMITING	2	08OCT2020	30/2	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C459100 1 1087 10871146	3^	PSYCH	Anxiety/ ANXIETY	1	09SEP2020	21/C	1	No	O	NA/TC/TCN	N	N/N
16-55/ C459100 1 1087 10871148	3^	GENRL	Pain/ Aches (generalized body)	2	14SEP2020	5/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100	3^	INJ&P	Muscle rupture/ LEFT BICEP TEAR	2	29SEP2020	19/1	2	No	O	NA/TCN	R (29SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1087 10871149	3^	BLOOD	Lymphadenopathy/ SWOLLEN LYMPH NODES IN LEFT AXILLA	2	12SEP2020	2/23	2	Yes		NA	R (04OCT2020)	N/N
1 1087 10871152	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	15SEP2020	2/5	1	Yes		NA	R (19SEP2020)	N/N
1 1087 10871172			Pyrexia/ FEVER	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1087 10871181	3^	MUSC	Myalgia/ generalized muscle Soreness	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1087 10871186	3^	INJ&P	Muscle strain/ RIGHT FOOT PAIN DUE TO STRAINING FOOT	1	05SEP2020	12/7	2	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1087 10871239	3^	GENRL	Pyrexia/ FEVER	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1087 10871252	3^	EAR	Vertigo/ VERTIGO	2	22SEP2020	5/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1087 10871299	3^	GENRL	Chills/ chills	2	24SEP2020	2/8	1	Yes		NA	R (01OCT2020)	N/N
			Fatigue/ fatigue	2	24SEP2020	2/8	1	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ fever	2	24SEP2020	2/8	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1087 10871343	3^	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1087 10871348	3^	RESP	Asthma/ ASTHMA EXACERBATION	1	30SEP2020	23/2	2	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1087 10871355	3^	BLOOD	Lymphadenopathy/ Swollen Right Cervical Lymph Node	2	05OCT2020	1/5	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1087 10871361	3^	GASTR	Nausea/ Nausea	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
		GENRL	Chills/ Chills	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1087 10871372	3^	GENRL	Pain/ Body Ache	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
		MUSC	Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Myalgia/ Generalized Muscle Soreness	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1087 10871471	3^	GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1087 10871487	3^	GENRL	Pyrexia/ Fever	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
			Chills/ Chills	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
			Fatigue/ Fatigue	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
16-55/ C459100 1 1087 10871491	3^	PSYCH	Insomnia/ Worsening of Insomnia	2	26OCT2020	20/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1088 10881213	3^	MUSC	Myalgia/ MUSCLE PAIN/ACHE	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1088 10881220	3^	NEOPL	Meningioma/ right frontal meningioma	1	23SEP2020	6/C	2	No	O	NA	N	Y/N
16-55/ C459100 1 1089 10891015	2^	INFEC	Tonsillitis/ Tonsillitis	2	14SEP2020	28/1	2	No	O	NA/TCN	R (14SEP2020)	N/N
16-55/ C459100 1 1089 10891025	3^	GENRL	Chills/ chills	2	29SEP2020	41/C	1	No	O	NA	N	N/N
			Pyrexia/ fever	2	29SEP2020	41/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1089 10891067	3^	MUSC	Muscle spasms/ back spasms	1	15AUG2020	10/10	2	No	O	NA/TC	R (24AUG2020)	N/N
16-55/ C459100 1 1089 10891103	3^	INFEC	Skin infection/ right knee superficial infection of the skin	1	28AUG2020	18/14	2	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1089 10891182	3^	RESP	Chronic obstructive pulmonary disease/ worsening of COPD	1	26AUG2020	2/2	2	No	O	NA/TC	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INJ&P	Fall/ Fall	1	09SEP2020	16/1	2	No	O	NA	R (09SEP2020)	N/N
			Hip fracture/ Left Hip Closed Fracture	1	09SEP2020	16/17	3	No	O	NA/TC	R (25SEP2020)	Y/N
		GASTR	Nausea/ nausea	1	27SEP2020	34/2	2	No	O	NA	R (28SEP2020)	N/N
		PSYCH	Psychotic disorder/ Psychosis	1	27SEP2020	34/C	3	No	O	NA/TC/TCN	N	Y/N
			Substance abuse/ worsening of polysubstance abuse	1	27SEP2020	34/2	2	No	O	NA	R (28SEP2020)	N/N
16-55/ C459100 1 1089 10891193	3^	IMMU N	Hypersensitivity/ worsening of allergies	1	08SEP2020	14/3	1	No	O	NA	R (10SEP2020)	N/N
16-55/ C459100 1 1089 10891207	3^	GENRL	Oedema peripheral/ bilateral edema legs	2	05NOV2020	49/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1089 10891253	3^	INFEC	Cellulitis/ left side facial cellulitis	1	11SEP2020	8/13	2	No	O	NA/TC	R (23SEP2020)	N/N
		GASTR	Swollen tongue/ swollen tounge	1	12SEP2020	9/4	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C459100 1 1089 10891261	3^	INFEC	Herpes zoster/ worsening shingles right bottom	1	19SEP2020	12/4	1	No	O	NA/TC	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1090 10901015	3^	GASTR	Diarrhoea/ diarrhea, single episode	2	04OCT2020	42/1	1	No	O	NA	R (04OCT2020)	N/N
16-55/ C459100 1 1090 10901020	3^	RESP	Oropharyngeal pain/ sore throat, intermittent	1	14AUG2020	12/5	1	No	O	NA	R (18AUG2020)	N/N
16-55/ C459100 1 1090 10901038	3^	RESP	Oropharyngeal pain/ sore throat	1	20AUG2020	17/4	2	No	O	NA	R (23AUG2020)	N/N
16-55/ C459100 1 1090 10901065	3^	NERV	Headache/ headaches, daily in afternoon	2	28AUG2020	1/47	2	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C459100 1 1090 10901094	3^	NERV	Burning sensation/ burning sensations, legs	1	18AUG2020	12/18	2	Yes		NA	R (04SEP2020)	N/N
		MUSC	Tendonitis/ tendonitis. right wrist	2	30SEP2020	34/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1090 10901147	3^	INFEC	Ear infection/ ear infection, both ears	2	01OCT2020	32/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1090 10901174	3^	MUSC	Muscle spasms/ muscle spasms, injection arm	2	04SEP2020	2/3	2	Yes		NA	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1090 10901187	3^	NERV	Facial paralysis/ Bell's Palsy right face	2	10SEP2020	3/3	1	Yes		NA/TC	RS (12SEP2020)	N/N
16-55/ C459100 1 1090 10901226	3^	GENRL	Chills/ Chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
			Pain/ Body aches	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ Headache	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1090 10901251	3^	RESP	Oropharyngeal pain/ sore throat	1	24AUG2020	6/5	2	No	O	NA	R (28AUG2020)	N/N
16-55/ C459100 1 1090 10901253	3^	GENRL	Chills/ Chills	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ Fever	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
		VASC	Hypertension/ High Blood pressure	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1090 10901277	3^	GENRL	Injection site pain/ Injection site pain	1	01SEP2020	1/4	2	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1090 10901291	3^	EAR	Ear pain/ Otalgia	1	02SEP2020	2/6	1	Yes		NA	R (07SEP2020)	N/N
		NERV	Headache/ Headache	1	03SEP2020	3/3	3	Yes		NA	R (05SEP2020)	N/N
		EAR	Ear pain/ otalgia, left ear	1	06SEP2020	5/3	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C459100 1 1090 10901294	3^	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/2	3	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1090 10901295	3^		Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	23SEP2020	1/2	3	Yes		NA	R (24SEP2020)	N/N
		GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Pain/ Body aches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	23SEP2020	1/1	2	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1090 10901316	3^	MUSC	Spinal stenosis/ Spinal Stenosis	2	29SEP2020	6/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1090 10901325	3^	GENRL	Chills/ Chills	1	23SEP2020	21/2	1	Yes		NA	R (24SEP2020)	N/N
			Fatigue/ Fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ fever	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1090 10901326	3^	GENRL	Injection site pain/ Left arm injection site pain	2	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N
			GENRL	Chills/ Chills	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)
		GENRL	Pyrexia/ Fever	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1090 10901355	3^	PSYCH	Anxiety/ worsening anxiety	1	23SEP2020	15/33	1	No	O	NA/TC	R (25OCT2020)	N/N
16-55/ C459100 1 1090 10901360	3^	GENRL	Chills/ Chills	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
			Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1090 10901366	3^	GENRL	Chills/ Chills	2	29SEP2020	1/2	3	Yes		NA	R (30SEP2020)	N/N
		MUSC	Arthralgia/ Generalized joint pains	2	29SEP2020	1/4	2	Yes		NA/TC	R (02OCT2020)	N/N
			Myalgia/ Generalized muscle aches	2	29SEP2020	1/4	2	Yes		NA/TC	R (02OCT2020)	N/N
		NERV	Headache/ Headache	2	29SEP2020	1/4	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1090 10901369	3^	MUSC	Arthralgia/ left shoulder pain	1	17SEP2020	8/8	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1090 10901373	3^	GENRL	Chills/ Chills	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
			Injection site pain/ Injection site pain-Left arm	1	10SEP2020	1/4	1	Yes		NA/TC	R (13SEP2020)	N/N
			Pain/ Generalized body aches	1	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
		NERV	Headache/ Headache	1	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		GENRL	Pyrexia/ Low grade fever	1	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1090 10901380		MUSC	Myalgia/ Muscle aches	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
		INJ&P	Fall/ Fall	2	12OCT2020	12/1	1	No	O	NA/TCN	R (12OCT2020)	N/N
			Skin laceration/ Forehead laceration	2	12OCT2020	12/C	2	No	O	NA/TCN	RG	N/N
16-55/ C459100 1 1090 10901383	3^	GENRL	Chills/ chills	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/Y
			Injection site pain/ Injection site pain	2	07OCT2020	1/4	2	Yes		NA/TC	R (10OCT2020)	N/Y
		NERV	Headache/ headache	2	08OCT2020	2/6	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C459100 1 1090 10901392	3^	GASTR	Nausea/ Nausea	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ Left arm injection site pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ Fever	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1090 10901394	3^	GENRL	Pyrexia/ fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		BLOOD	Lymphadenopathy/ Swollen lymph nodes-left axilla	2	07OCT2020	2/28	3	Yes		NA	R (03NOV2020)	N/N
		GENRL	Fatigue/ fatigue	2	07OCT2020	2/4	2	Yes		NA	R (10OCT2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1090 10901397	3^	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	1/5	1	Yes		NA/TC	R (19SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	1	17SEP2020	3/1	1	Yes		NA/TC	R (17SEP2020)	N/N
		NERV	Headache/ Headache	1	17SEP2020	3/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1090 10901398	3^	MUSC	Exostosis/ Bone spur-right knee	2	06NOV2020	31/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1090 10901407	3^	GENRL	Injection site pain/ injection side pain, left arm	1	17SEP2020	2/8	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ left arm injection pain	1	25SEP2020	10/C	1	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1090 10901410	3^	GENRL	Fatigue/ Fatigue	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	09OCT2020	1/1	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1090 10901417	3^	GENRL	Injection site pain/ Injection site pain-left arm	1	18SEP2020	2/8	2	Yes		NA/TC	R (25SEP2020)	N/N
		NERV	Headache/ Headache	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain-Left arm	2	08OCT2020	2/7	2	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1090 10901422	3^	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1090 10901429	3^	GENRL	Injection site pain/ Injection site pain-left arm	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C459100 1 1090 10901432	3^	GENRL	Pyrexia/ Fever	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1090 10901441	3^	MUSC	Myalgia/ Muscle aches	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	13OCT2020	2/4	2	Yes		NA	R (16OCT2020)	N/N
			Pyrexia/ Fever	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	13OCT2020	2/3	2	Yes		NA	R (15OCT2020)	N/N
		GENRL	Chills/ Chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
			Fatigue/ Fatigue	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
			Pyrexia/ Fever	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		NERV	Headache/ Headache	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Pain/ Body aches	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
		16-55/ C459100 1 1090 10901452	3^	INJ&P	Arthropod bite/ Insect bite-Hornet	1	29SEP2020	7/10	1	No	O	NA/TC
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1090 10901457			Injection site pain/ Injection site pain-left arm	2	15OCT2020	2/5	2	Yes		NA/TC	R (19OCT2020)	N/N
			Pyrexia/ Fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1090 10901461	3^	GENRL	Injection site pain/ Injection site pain-left arm	2	16OCT2020	1/4	1	Yes		NA	R (19OCT2020)	N/Y
		GENRL	Pain/ Body aches	2	17OCT2020	2/4	2	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1090 10901465	3^	GENRL	Injection site pain/ Injection site pain-left arm	2	13OCT2020	1/3	2	Yes		NA	RS (15OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	14OCT2020	2/4	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1090 10901477	3^	GENRL	Chills/ chills	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
			Fatigue/ Fatigue	1	26SEP2020	2/1	2	Yes		NA	R (26SEP2020)	N/N
			Pain/ Body aches	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100	3^	GENRL	Pain/ Body aches	2	14OCT2020	1/4	1	Yes		NA/TC	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1090 10901480		MUSC	Myalgia/ Muscle aches	2	14OCT2020	1/4	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 1090 10901482	3^	MUSC	Myalgia/ Cervical myalgia	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1091 10911008	3^	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	02SEP2020	14/C	1	No	O	NA	N	N/N
		VASC	Hypertension/ hypertension	2	02SEP2020	14/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1091 10911032	3^	INFEC	Otitis media/ otitis media	2	07SEP2020	15/9	2	No	O	NA/TC	R (15SEP2020)	N/N
16-55/ C459100 1 1091 10911123	3^	GENRL	Injection site pain/ injection site tenderness	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
		GENRL	Fatigue/ fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1091 10911134	3^	GENRL	Fatigue/ fatigue	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)		
16-55/ C459100 1 1091 10911144	3^	MUSC	Injection site pain/ injection site soreness	1	18AUG2020	1/4	1	Yes		NA/TC	R (21AUG2020)	N/N		
			Myalgia/ muscle aches	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N		
		GENRL	Injection site bruising/ injection site bruising	1	19AUG2020	2/4	1	Yes		NA	R (22AUG2020)	N/N		
		GENRL	Fatigue/ fatigue	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N		
			Injection site bruising/ injection site bruising	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N		
			Injection site pain/ injection site soreness	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N		
		MUSC	Myalgia/ muscle aches	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N		
		MUSC	Myalgia/ myalgia	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N		
		16-55/ C459100 1 1091 10911146	3^	NERV	Headache/ intermittent headaches	1	20AUG2020	2/11	1	Yes		NA/TC	R (30AUG2020)	N/N
			GENRL	Chills/ chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
		Malaise/ malaise	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N			
16-55/ C459100	3^	GENRL	Pain/ body aches	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1091 10911156	3^	GENRL	Injection site pain/ soreness at injection site	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
1 1091 10911162			Pain/ body aches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		INJ&P	Muscle strain/ Right bicep muscle strain	2	16OCT2020	33/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1091 10911169	3^	PSYCH	Anxiety/ anxiety	2	26SEP2020	12/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1091 10911174	3^	GENRL	Injection site pain/ soreness at injection site	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 1 1091 10911182	3^	GENRL	Injection site pain/ injection site pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Chills/ chills	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ injection site pain	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ fever	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1091 10911189	3^	MUSC	Myalgia/ worsening myalgias	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ worsening headache	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Tendonitis/ left bicep tendonitis	2	15SEP2020	1/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1091 10911196	3^	GENRL	Fatigue/ fatigue	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1091 10911197	3^	MUSC	Myalgia/ generalized muscle pain	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ headaches	2	08OCT2020	22/C	1	No	O	NA	N	N/N
		GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	1/17	1	Yes		NA	R (03OCT2020)	N/N
		INJ&P	Toxicity to various agents/ poisoning by cocaine	2	26SEP2020	10/2	4	No	O	NA/TC/TCN	R (27SEP2020)	Y/N
		RESP	Hypoxia/ hypoxia	2	26SEP2020	10/2	3	No	O	NA/TC/TCN	R (27SEP2020)	Y/N
			Pneumonia aspiration/ Aspiration Pneumonia	2	26SEP2020	10/11	3	No	O	NA/TC	R (06OCT2020)	Y/N
		RESP	Nasal congestion/ nasal congestion	2	10OCT2020	24/8	1	No	O	NA	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1091 10911202	3^	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ headache	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1091 10911207	3^	GENRL	Injection site pain/ soreness at injection site	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1091 10911208	3^	GENRL	Fatigue/ Fatigue	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
			Injection site pain/ Injection site pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		MUSC	Arthralgia/ Joint pain	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
		NERV	Headache/ Headache	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
16-55/ C459100 1 1091 10911219	3^	GENRL	Injection site pain/ L arm injection site pain	2	21SEP2020	1/5	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1091 10911220	3^	GENRL	Chills/ Chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
			Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 1 1091 10911226	3^	GENRL	Injection site pain/ injection site soreness	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1091 10911232	3^	GENRL	Injection site pain/ left injection-site pain	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1091 10911237	3^	GENRL	Injection site pain/ L injection site pain	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ L arm injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Chills/ Chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
			Fatigue/ Fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1091 10911239	3^	GENRL	Injection site pain/ soreness at injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		RESP	Epistaxis/ epistaxis	1	23SEP2020	22/1	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C459100 1 1091 10911250	3^	GENRL	Injection site pain/ soreness at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
		MUSC	Myalgia/ generalized muscle aches	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1091 10911252	3^	GENRL	Injection site pain/ Injection site pain	2	29SEP2020	1/4	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1091 10911256	3^	INJ&P	Muscle strain/ worsening back strain	1	09SEP2020	2/C	1	No	O	NA/TC	RG	N/N
		GENRL	Injection site pain/ site injection pain	2	15OCT2020	2/C	1	Yes		NA	RG	N/N
		MUSC	Myalgia/ Myalgia	2	15OCT2020	2/C	1	Yes		NA	RG	N/N
		NERV	Headache/ Headache	2	15OCT2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ injection site soreness	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1091 10911270	3^	GENRL	Chills/ chills (without fever)	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
1 1091 10911277	3^	GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
1 1091 10911279		GENRL	Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Malaise/ Malaise	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1091 10911283	3^	GENRL	Injection site pain/ Injection Site Soreness	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1091 10911289	3^	NERV	Headache/ headache	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1091 10911290	3^	GENRL	Injection site pain/ injection site soreness	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1091 10911291	3^	MUSC	Metatarsalgia/ worsening of metatarsalgia	1	21SEP2020	11/16	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1091 10911293	3^	INJ&P	Muscle rupture/ R Deltoid Tear	1	20SEP2020	7/C	2	No	O	NA/TCN	RG	N/N
		NEOPL	Lipoma/ Right deltoid lipoma	1	20SEP2020	7/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1091 10911297	3^	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	1	02OCT2020	19/4	1	No	O	NA/TC	R (05OCT2020)	N/N
16-55/ C459100 1 1091 10911300	3^	GENRL	Injection site pain/ soreness at injection site	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/ Injection Site Pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		INFEC	Appendicitis/ Appendicitis	2	22OCT2020	17/2	4	No	O	NA/TCN	R (23OCT2020)	Y/N
16-55/ C459100 1 1091 10911301	3^	GENRL	Chills/ Chills	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1091 10911306	3^	GENRL	Fatigue/ Fatigue	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N	
			Malaise/ Maliase	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	
			Insomnia/ Insomnia	2	08OCT2020	1/2	1	No	O		NA	R (09OCT2020)	N/N
			Injection site pain/ pain at injection site	2	07OCT2020	1/3	1	Yes			NA	R (09OCT2020)	N/N
				2	08OCT2020	2/2	1	Yes			NA	R (09OCT2020)	N/N
16-55/ C459100 1 1091 10911310	3^	GENRL	Pyrexia/ Fever	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
			Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N	
			Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N	
16-55/ C459100 1 1091 10911313	3^	MUSC	Injection site pain/ Injection Site Pain	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N	
			Myalgia/ Muscle Pain	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N	
			Otitis media/ Serous Otitis Media, R ear	2	29OCT2020	23/4	1	No	O		NA	R (01NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1091 10911315	3^	INJ&P	Tendon rupture/ Tear of bicep tendon	1	23SEP2020	7/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1091 10911320	3^	GENRL	Chills/ chills	2	11OCT2020	4/3	2	Yes		NA	R (13OCT2020)	N/N
			Fatigue/ fatigue	2	11OCT2020	4/3	2	Yes		NA	R (13OCT2020)	N/N
		NERV	Headache/ headache	2	11OCT2020	4/3	2	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1091 10911321	3^	INJ&P	Spinal compression fracture/ worsening of compression fracture in spine	2	OCT2020	1/C	1	No	O	NA	RG	N/N
		GENRL	Fatigue/ fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		MUSC	Arthralgia/ Generalized joint pain	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
			Myalgia/ muscle pain	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1091 10911336	3^	GASTR	Nausea/ Nausea	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1091 10911340	3^	GENRL	Pyrexia/ Fever	2	13OCT2020	2/3	1	Yes		NA/TC	R (15OCT2020)	N/N	
			MUSC	Myalgia/ Myalgias	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
			GENRL	Injection site pain/ left arm injection site pain	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/Y
16-55/ C459100 1 1091 10911341	3^	GENRL	Chills/ chills	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N	
16-55/ C459100 1 1091 10911342	3^	GENRL	Fatigue/ fatigue	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N	
			GENRL	Pyrexia/ fever	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
			GENRL	Pyrexia/ Fever	2	14OCT2020	1/3	2	Yes		NA/TC	R (16OCT2020)	N/N
			MUSC	Myalgia/ Myalgias	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1091 10911343	3^	GENRL	NERV	Headache/ Headache	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
			GENRL	Injection site pain/ injection site soreness	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1091 10911344	3^	NERV	Headache/ Headache	1	29SEP2020	1/1	1	Yes		NA	R (29SEP2020)	N/N
		GASTR	Nausea/ nausea	1	17OCT2020	19/1	1	No	O	NA	R (17OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	21OCT2020	3/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1091 10911348	3^	GENRL	Injection site pain/ L arm injection site pain	1	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1091 10911351	3^	GENRL	Injection site pain/ pain at injection site	1	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1091 10911356	3^	NERV	Headache/ headache	2	29OCT2020	2/1	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C459100 1 1092 10921033	3^	INJ&P	Muscle strain/ muscle strain lower back	2	03OCT2020	26/14	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1092 10921035	3^	GENRL	Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100	3^	INFEC	Otitis media/ left otitis media	1	01SEP2020	9/11	1	No	O	NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1092 10921045			Sinusitis/ sinus infection	1	01SEP2020	9/11	1	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1092 10921065	3^	GENRL	Injection site erythema/ Injection site redness	1	25AUG2020	1/5	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Injection site pain/ injection site tenderness	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ fever	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ myalgia	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1092 10921081	3^	EAR	Ear pain/ Earache	2	18SEP2020	3/10	1	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C459100 1 1092 10921098	3^	INFEC	Rhinitis/ Coryza	2	20SEP2020	4/12	1	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1092 10921099	3^	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Pain/ Body Aches	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1092 10921106	3^	IN FEC	Urinary tract infection/ urinary tract infection	2	08OCT2020	18/9	1	No	O	NA/TC	R (16OCT2020)	N/N
		SKIN	Rash/ scattered Rash	2	15OCT2020	25/3	1	No	O	NA	R (17OCT2020)	N/N
16-55/ C459100 1 1092 10921122	3^	GEN RL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
			Injection site pain/ Injection site soreness	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
			Pyrexia/ fever	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 1 1092 10921130	3^	RESP	Epistaxis/ intermittent bilateral nose bleed	2	12OCT2020	21/29	1	No	O	NA	R (09NOV2020)	N/N
16-55/ C459100 1 1092 10921132	3^	GEN RL	Fatigue/ fatigue	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/Y
16-55/ C459100 1 1092 10921139	3^	NER V	Sciatica/ Sciatica	2	28SEP2020	6/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1092 10921142	3^	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		INV	Blood pressure increased/ Elevated Blood Pressure	2	24SEP2020	1/2	1	No	O	NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Lethargy/ Lethargy	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1092 10921143	3^	GENRL	Injection site pain/ injection site soreness	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
			Injection site papule/ Injection site papule	1	03SEP2020	2/C	1	Yes		NA	RG	N/N
			Pyrexia/ fever	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
16-55/ C459100 1 1092 10921146	3^	GENRL	Injection site pain/ injection site pain	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N
			Pyrexia/ fever	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N
		MUSC	Back pain/ back ache	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N
			Myalgia/ myalgia	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1092 10921153	3^	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1092 10921168	3^	GENRL	Chills/ Chills	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
			Injection site pain/ Injection site tenderness	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
			Malaise/ Malaise	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
			Pyrexia/ Fever	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		NERV	Headache/ Headache	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Chills/ Chills	2	29SEP2020	1/1	1	Yes		NA	R (29SEP2020)	N/N
			Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Pyrexia/ Fever	2	29SEP2020	1/1	1	Yes		NA/TC	R (29SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1092 10921186	3^	MUSC	Osteoarthritis/ worsening osteoarthritis	2	02NOV2020	29/C	2	No	O	NA	N	N/N
16-55/ C459100 1 1093 10931058	3^	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	28AUG2020	4/C		No	O	P	UNK	N/N
16-55/ C459100 1 1093 10931111	3^	RESP	Rhinorrhoea/ RUNNY NOSE	1	16SEP2020	9/5	1	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C459100 1 1093 10931134	3^	METAB	Glucose tolerance impaired/ PRE-DIABETES	2	30OCT2020	17/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1094 10941070	3^	MUSC	Back pain/ Back pain	1	21SEP2020	25/5	2	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1094 10941098	3^	MUSC	Back pain/ Back Pain	2	30SEP2020	3/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1094 10941132	3^	SKIN	Hyperhidrosis/ sweat	1	19SEP2020	5/3	2	No	O	NA	R (21SEP2020)	N/N
16-55/ C459100	3^	INJ&P	Colon injury/ colon injury	1	16OCT2020	22/8	3	No	O	NA/TC/TCN	RS (23OCT2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11094 10941155			Road traffic accident/ motor vehicle accident	1	16OCT2020	22/1	3	No	O	NA	R (16OCT2020)	N/N
16-55/ C459100 11095 10951001	2^	MUSC	Arthralgia/ left knee pain	1	17AUG2020	19/1	1	No	O	NA/TC	R (17AUG2020)	N/N
16-55/ C459100 11095 10951005	2^	MUSC	Arthralgia/ polyarthralgias	1	06AUG2020	8/C	1	No	O	NA	N	N/N
		INFEC	Gastroenteritis viral/ viral gastroenteritis	2	01SEP2020	15/1	1	No	O	NA	R (01SEP2020)	N/N
16-55/ C459100 11095 10951023	3^	INFEC	Diverticulitis/ Diverticulitis flare	1	20AUG2020	18/5	1	No	O	NA/TC	R (24AUG2020)	N/N
16-55/ C459100 11095 10951026	3^	METAB	Decreased appetite/ Loss of appetite	1	13AUG2020	11/C	1	No	O	NA	RG	N/N
		INJ&P	Fall/ Fall	1	23AUG2020	21/1	1	No	O	NA	R (23AUG2020)	N/N
			Skin abrasion/ Left arm abrasions	1	23AUG2020	21/8	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C459100	3^	RESP	Rhinitis allergic/ allergic rhinitis	2	03SEP2020	11/2	1	No	O	NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1095 10951029		GASTR	Diarrhoea/ diarrhea	2	04SEP2020	12/2	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C459100 1 1095 10951047	3^	INJ&P	Rib fracture/ Rib fracture	2	30AUG2020	6/33	1	No	O	NA/TC	R (01OCT2020)	N/N
		GENRL	Malaise/ idiopathic malaise	2	31AUG2020	7/2	1	No	O	NA	R (01SEP2020)	N/N
16-55/ C459100 1 1095 10951055	3^	REPRO	Cervical dysplasia/ ASCUS of cervix	1	10AUG2020	7/18	1	No	O	NA/TC	R (27AUG2020)	N/N
16-55/ C459100 1 1095 10951062	3^	INJ&P	Arthropod bite/ nonvenomous insect bite of right elbow	1	17AUG2020	13/1	1	No	O	NA/TC	R (17AUG2020)	N/N
		IMMUN	Seasonal allergy/ seasonal allergies	2	14SEP2020	20/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1095 10951087	3^	GENRL	Fatigue/ Fatigue	1	12AUG2020	7/2	1	No	O	NA	R (13AUG2020)	N/N
16-55/ C459100 1 1095 10951095	3^	RESP	Rhinitis allergic/ allergic rhinitis	1	17AUG2020	11/5	1	No	O	NA	R (21AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1095 10951106	3^	MUSC	Arthralgia/ polyarthralgia	2	03SEP2020	7/2	1	No	O	NA	R (04SEP2020)	N/N
16-55/ C459100 1 1095 10951112	3^	GASTR	Nausea/ Nausea	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
		MUSC	Myalgia/ Myalgia	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
		NERV	Headache/ Headache	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site Tenderness	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N
		VASC	Hot flush/ Hot Flashes	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Sinus headache/ Sinus Headache	2	25SEP2020	10/2	1	No	O	NA/TC	R (26SEP2020)	N/N
16-55/ C459100 1 1095 10951116	3^	GENRL	Fatigue/ fatigue	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ Generalized myalgias	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1095 10951124	3^	SKIN	Dermatitis contact/ Dermatitis-poison ivy	1	12SEP2020	20/5	1	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1095 10951129	3^	MUSC	Myalgia/ Myalgia post vaccine	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1095 10951132	3^	INV	Body temperature increased/ Elevated Body Temperature	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		MUSC	Myalgia/ Myalgia post vaccination	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ Headache post vaccination	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1095 10951138	3^	GENRL	Injection site pain/ left arm (deltoid) injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 1 1095 10951141	3^	SKIN	Diabetic foot/ Diabetic Foot Ulcer R Foot	1	14SEP2020	20/C	1	No	O	NA/TCN/W	N	N/N
16-55/ C459100 1 1095 10951144	3^	GENRL	Injection site pain/ pain right shoulder injection site (serapin)	1	09SEP2020	15/5	1	No	O	NA/TC	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1095 10951148	3^	GENRL	Chills/ Chills post vaccination	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Fatigue/ Fatigue post vaccination	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1095 10951149	3^	INV	Body temperature increased/ elevated temperature	1	13SEP2020	18/2	1	Yes		NA/TC	R (14SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1095 10951150	3^	INFEC	Soft tissue infection/ soft tissue infection left leg*		JUN2020		1	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1095 10951153	3^	GENRL	Injection site pain/ injection site pain left arm	2	22SEP2020	1/6	1	Yes		NA/TC	R (27SEP2020)	N/N
			Pyrexia/ fever post vaccination	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ myalgia post vaccination	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1095 10951154	3^	NERV	Headache/ headache post vaccination	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		GASTR	Nausea/ nausea post vaccination	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain left arm	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/Y
16-55/ C459100 1 1095 10951156	3^	GENRL	Injection site pain/ Injection site pain left arm	1	29AUG2020	2/4	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C459100 1 1095 10951159	3^	GENRL	Chills/ Post vaccine chills	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Fatigue/ Post vaccine fatigue	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Pyrexia/ Post vaccine fever	2	16SEP2020	1/2	3	Yes		NA/TC	R (17SEP2020)	N/N
		NERV	Headache/ Post vaccine headache	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain right arm	1	29AUG2020	1/4	1	Yes		NA	R (01SEP2020)	N/Y
		GENRL	Chills/ Chills	2	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1095 10951160	3^	GENRL	Injection site warmth/ Warmth at injection site	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
			Vaccination site pain/ Pain at injection site post vaccination	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
			Fatigue/ Fatigue post vaccination	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1095 10951161	3^	GENRL	Injection site pain/ injection site reaction left arm myalgia	1	29AUG2020	1/3	1	Yes		NA	R (31AUG2020)	N/N
			Injection site pain/ injection site pain left arm	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1095 10951168	3^	MUSC	Arthralgia/ Arthralgia post vaccine	1	29AUG2020	1/3	2	Yes		NA/TC	R (31AUG2020)	N/N
		SOCCI	Menopause/ Perimenopausal	1	14SEP2020	17/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1095 10951170	3^	NERV	Headache/ Headache	1	29AUG2020	1/3	1	Yes		NA/TC	R (31AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain left arm	1	30AUG2020	2/3	1	Yes		NA/TC	R (01SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1095 10951171	3^	MUSC	Myalgia/ Myalgias	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		SKIN	Dermatitis contact/ Contact Dermatitis Left Arm	1	29AUG2020	1/2	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 1 1095 10951173	3^	CARD	Acute myocardial infarction/ STEMI: ST elevation Myocardial Infarction	1	05SEP2020	8/5	4	No	O	P/TC/TCN	R (09SEP2020)	Y/N
16-55/ C459100 1 1095 10951174	3^	UNC	CORONARY ARTERY DISEASE@@/ Coronary Artery Disease	1	05SEP2020	8/C	2	No	O	NA	N	N/N
		MUSC	Myalgia/ Myalgia	1	09SEP2020	10/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain right arm	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1095 10951176	3^	MUSC	Myalgia/ post vaccination myalgia	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ post vaccination headache	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Injection site pain/ injection site myalgia left arm	1	03SEP2020	1/7	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1095 10951177	3^	GENRL	Injection site pain/ Pain at injection site left arm	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
1 1095 10951178	3^	GENRL	Injection site pain/ Injection site pain	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
1 1095 10951182		GENRL	Chills/ Generalized Rigors	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		INV	Body temperature increased/ elevated temperature	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ generalized myalgia	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1095 10951183	3^	GENRL	Chills/ chills without fever	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Fatigue/ fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1095 10951186	3^	INJ&P	Tendon injury/ left finger tendon injury	2	26SEP2020	6/C	1	No	O	NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1095 10951188	3^	GENRL	Pyrexia/ fever	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Myalgia/ myalgia post vaccination	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1095 10951196	3^	INJ&P	Ligament sprain/ Right wrist sprain	1	08SEP2020	8/29	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C459100 1 1095 10951197	3^	SKIN	Drug eruption/ Fixed drug eruption on feet bilaterally	2	26OCT2020	8/C	2	Yes		NA	N	N/N
16-55/ C459100 1 1095 10951198	3^	MUSC	Myalgia/ post vaccination myalgia	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ Injection Site pain Left Arm	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/Y
		MUSC	Myalgia/ Myalgia	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1095 10951199	3^	GENRL	Injection site pain/ injection site reaction myalgia	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1095 10951208	3^	GENRL	Injection site pain/ myalgia due to intramuscular injection into deltoid muscle	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		INFEC	Tooth infection/ tooth infection	1	23SEP2020	22/16	1	No	O	NA/TC	R (08OCT2020)	N/N
		ENDO	Hypothyroidism/ worsening of hypothyroidism	1	08OCT2020	37/C	1	No	O	NA/TC	UNK	N/N
16-55/ C459100 1 1095 10951218	3^	GENRL	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		SKIN	Hyperhidrosis/ Diaphoresis	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1095 10951225	3^	GENRL	Injection site pain/ injection site left deltoid muscle pain	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N
		MUSC	Myalgia/ myalgia	1	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N
		INV	Body temperature increased/ elevated temperature	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100 1 1095 10951233	3^	GENRL	Pyrexia/ Fever	2	15OCT2020	2/1	2	Yes		NA/TC	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1095 10951241	3^	GENRL	Injection site pain/ Injection site myalgia left arm	1	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Fatigue/ generalized fatigue	1	20OCT2020	21/2	1	No	O	NA	R (21OCT2020)	N/N
		GENRL	Fatigue/ generalized fatigue	1	30OCT2020	31/2	2	No	O	NA	R (31OCT2020)	N/N
16-55/ C459100 1 1095 10951250	3^	GENRL	Injection site pain/ injection site pain	2	20OCT2020	1/C	1	Yes		NA	N	N/Y
16-55/ C459100 1 1095 10951251	3^	GENRL	Fatigue/ Fatigue	1	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Myalgia/ Myalgia post vaccination	1	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
			Injection site pain/ pain at injection site left arm	2	20OCT2020	1/6	1	Yes		NA	R (25OCT2020)	N/N
			Injection site swelling/ swelling at injection site left arm	2	20OCT2020	1/6	1	Yes		NA	R (25OCT2020)	N/N
			Injection site warmth/ warmth at injection site left arm	2	20OCT2020	1/6	1	Yes		NA	R (25OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1095 10951255	3^	NERV	Headache/ worsening headache	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
		GENRL	Vaccination site pain/ pain at injection site left arm post vaccine	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1095 10951257	3^	UNC	INJECTION SITE PAIN LEFT ARM@@/ Injection Site Pain Left Arm	2	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N
		GENRL	Fatigue/ fatigue	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1095 10951266	3^	GENRL	Injection site pain/ injection site pain left arm	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ left arm pain at injection site	1	08OCT2020	1/5	1	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C459100 1 1095 10951267	3^	GENRL	Injection site pain/ injection site pain left arm	2	28OCT2020	1/2	1	Yes		NA/TC	R (29OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N
		GENRL	Chills/ chills	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1096 10961027	3^	GENRL	Pyrexia/ Fever	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N	
			MUSC	Myalgia/ myalgias	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
			NERV	Headache/ mild headache	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
			GENRL	Fatigue/ Fatigue	2	10SEP2020	7/1	2	Yes		NA	R (10SEP2020)	N/N
			MUSC	Arthralgia/ Joint pain	2	10SEP2020	7/1	1	Yes		NA	R (10SEP2020)	N/N
			MUSC	Myalgia/ Generalized muscle pain	2	10SEP2020	7/1	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1096 10961031	3^	INJ&P	Headache/ Headache	2	10SEP2020	7/1	1	Yes		NA	R (10SEP2020)	N/N	
			INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	14AUG2020	1/40		No	O	P	R (22SEP2020)	N/N
			RESP	Nasal congestion/ Nasal congestion	1	05OCT2020	53/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1096 10961042	3^	GENRL	Oropharyngeal pain/ Sore throat	1	05OCT2020	53/3	1	No	O	NA	R (07OCT2020)	N/N	
			GENRL	Pyrexia/ Fever	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1096 10961059	3^	GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	7/4	2	Yes		NA/TC	R (28AUG2020)	N/N
16-55/ C459100 1 1096 10961062	3^	METAB	Hypokalaemia/ HYPOKALEMIA	2	SEP2020	1/	3	No	O	NA/TC	R	Y/N
		VASC	Hypertension/ worsening of hypertension	2	14SEP2020	6/C	1	No	O	NA/TC	N	N/N
		NERV	Diplegia/ Bilateral Lower extremity paralysis	2	04OCT2020	26/2	3	No	O	NA	R (05OCT2020)	Y/N
16-55/ C459100 1 1096 10961063	3^	MUSC	Muscle spasms/ left upper arm Muscle spasms	1	22AUG2020	4/2	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C459100 1 1096 10961078	3^	RESP	Cough/ Cough	1	01SEP2020	13/4	1	No	O	NA	R (04SEP2020)	N/N
16-55/ C459100 1 1096 10961088	3^	GASTR	Dyspepsia/ Indigestion	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Arthralgia/ Joint pain in both elbows and knees	2	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1096 10961090	3^	INJ&P	Limb injury/ Right arm injury	2	19SEP2020	9/1	2	No	O	NA/TC	R (19SEP2020)	N/N
			Road traffic accident/ motor vehicle accident	2	19SEP2020	9/1	2	No	O	NA/TC	R (19SEP2020)	N/N
		MUSC	Pain in extremity/ Right arm pain	2	19SEP2020	9/C	2	No	O	NA	N	N/N
16-55/ C459100 1 1096 10961097	3^	NERV	Headache/ Intermittent headaches	2	13SEP2020	2/3	1	Yes		NA/TC	R (15SEP2020)	N/N
		UNC	GENERALIZED RASH ON BODY@@/ generalized rash on body	2	13SEP2020	2/6	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1096 10961098	3^	PSYCH	Insomnia/ Insomnia	2	06OCT2020	25/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1096 10961115	3^	RESP	Oropharyngeal pain/ Sore throat	1	12SEP2020	20/8	1	No	O	NA	R (19SEP2020)	N/N
16-55/ C459100 1 1096 10961130	3^	NERV	Tension headache/ stress headaches	1	26AUG2020	2/23	1	No	O	NA/TC	R (17SEP2020)	N/N
16-55/ C459100	3^	INJ&P	Concussion/ concussion	1	13SEP2020	19/5	2	No	O	NA/TC	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1096 10961137												
16-55/ C459100	3^	METAB	Vitamin D deficiency/ VITAMIN D DEFICIENCY	2	06OCT2020	21/C	1	No	O	NA/TC	N	N/N
1 1096 10961138		PSYCH	Anxiety/ worsening of anxiety	2	06OCT2020	21/C	1	No	O	NA/TC	N	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	27AUG2020	2/4	1	Yes		NA	R (30AUG2020)	N/N
1 1096 10961141												
16-55/ C459100	3^	INFEC	Ear infection/ Right ear infection	1	13SEP2020	18/5	1	No	O	NA/TC	R (17SEP2020)	N/N
1 1096 10961150												
16-55/ C459100	3^	GASTR	Flatulence/ gassiness	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
1 1096 10961169												
		GENRL	Chills/ chills	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
			Fatigue/ fatigue	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
			Injection site pain/ injection site tenderness	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
			Pyrexia/ fever	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ headache	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 1 1096 10961186	3^	GENRL	Injection site pain/ injection site soreness*		29AUG2020	1/3	2	Yes		NA	R (31AUG2020)	N/N
16-55/ C459100 1 1096 10961206	3^	NERV	Headache/ Intermittent Headaches	1	02SEP2020	2/38	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1096 10961207	3^	INJ&P	Epicondylitis/ lateral epicondylitis of the left elbow	1	09SEP2020	9/C	1	No	O	NA	N	N/N
		SKIN	Dermatitis contact/ Contact dermatitis on left arm	1	19SEP2020	19/17	1	No	O	NA/TC	R (05OCT2020)	N/N
16-55/ C459100 1 1096 10961208	3^	SKIN	Hyperhidrosis/ Sweating	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 1 1096 10961209	3^	RESP	Nasal congestion/ Nasal congestion	1	16SEP2020	16/5	1	No	O	NA	R (20SEP2020)	N/N
			Oropharyngeal pain/ Sore throat	1	16SEP2020	16/3	1	No	O	NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1096 10961213	3^	GENRL	Fatigue/ Fatigue	1	02SEP2020	1/3	2	Yes		NA	R (04SEP2020)	N/N
			Injection site pain/ Injection site soreness	1	02SEP2020	1/3	2	Yes		NA	R (04SEP2020)	N/N
		MUSC	Myalgia/ Generalized muscle pain	1	02SEP2020	1/3	2	Yes		NA/TC	R (04SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N
		MUSC	Myalgia/ Generalized muscle pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1096 10961215	3^	GASTR	Nausea/ Nausea	1	07SEP2020	6/9	1	No	CND	NA/TC	R (15SEP2020)	N/N
16-55/ C459100 1 1096 10961219	3^	GENRL	Chills/ CHILLS	1	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N
			Pain/ BODY ACHES	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
			Pyrexia/ FEVER	1	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE SORENESS	1	04SEP2020	3/3	1	Yes		NA/TC	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1096 10961226	3^	GENRL	Injection site pain/ Injection site soreness*		03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1096 10961236	3^	GENRL	Chills/ Chills	2	26SEP2020	1/2	1	Yes		NA	R (27SEP2020)	N/N
			Pyrexia/ Fever (102F max)	2	26SEP2020	1/2	2	Yes		NA	R (27SEP2020)	N/N
		MUSC	Myalgia/ Generalized muscle aches	2	26SEP2020	1/2	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ Headache	2	27SEP2020	2/2	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C459100 1 1096 10961240	3^	NERV	Presyncope/ presyncope	1	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/Y
		GASTR	Nausea/ Nausea	2	30SEP2020	8/3	1	No	O	NA	R (02OCT2020)	N/N
			Vomiting/ Vomiting	2	30SEP2020	8/3	1	No	O	NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	30SEP2020	8/3	1	No	O	NA	R (02OCT2020)	N/N
16-55/ C459100 1 1096 10961244	3^	INFEC	Conjunctivitis/ left eye conjunctivitis	2	17OCT2020	25/8	1	No	O	NA/TC	R (24OCT2020)	N/N
16-55/ C459100 1 1096 10961255	3^	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	20/2	1	Yes		NA	R (24SEP2020)	N/N
		PSYCH	Anxiety/ Worsening of anxiety	2	08OCT2020	16/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1096 10961256	3^	NERV	Dizziness/ Lightheaded*		04SEP2020	1/1	1	No	O	NA	R (04SEP2020)	N/N
16-55/ C459100 1 1096 10961262	3^	GENRL	Injection site erythema/ Injection site redness on left arm (3 units on sponsor's caliper)	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/Y
		GENRL	Fatigue/ Fatigue	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
			Injection site pain/ Injection site pain	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
		MUSC	Myalgia/ Generalized muscle aches	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100	3^	INJ&P	Road traffic accident/ motor vehicle accident	2	24OCT2020	30/1	1	No	O	NA	R (24OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1096 10961264		GENRL	Pain/ generalized body aches	2	26OCT2020	32/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1096 10961265	3^	GENRL	Injection site erythema/ injection site redness left upper arm	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
			Injection site pain/ Injection site pain left upper arm	2	24SEP2020	1/5	2	Yes		NA	R (28SEP2020)	N/N
		MUSC	Myalgia/ General muscle aches	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1096 10961267	3^	GENRL	Injection site pain/ Injection site soreness (left arm)	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C459100 1 1096 10961271	3^	GASTR	Nausea/ NAUSEA	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Pain/ BODY ACHE	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		VASC	Hot flush/ INTERMITTENT HOT FLAHERS	2	25SEP2020	2/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1096 10961275	3^	GENRL	Injection site pain/ Injection site soreness	1	05SEP2020	1/3	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C459100 1 1096 10961277	3^	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	1/3	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C459100 1 1096 10961278	3^	BLOOD	Lymphadenopathy/ Right swollen lymph node under jaw	1	13SEP2020	9/4	1	No	O	NA	R (16SEP2020)	N/N
		INFEC	Sialoadenitis/ Sialadenitis	1	13SEP2020	9/4	1	No	O	NA	R (16SEP2020)	N/N
		RESP	Oropharyngeal pain/ Sore throat	1	13SEP2020	9/2	1	No	O	NA/TC	R (14SEP2020)	N/N
		MUSC	Myalgia/ Generalized muscle aches due to exercise	1	22SEP2020	18/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1096 10961280	3^	GENRL	Chills/ Chills	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
			Injection site pain/ Injection site soreness	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 1 1096 10961299	3^	GENRL	Injection site swelling/ Injection site swelling	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1096 10961301	3^	INFEC	Tooth infection/ tooth infection	1	15SEP2020	8/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1096 10961307	3^	GENRL	Fatigue/ fatigue	2	07OCT2020	6/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1096 10961348	3^	GENRL	Injection site pain/ Injection site soreness	1	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
		MUSC	Myalgia/ Generalized muscle aches	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1096 10961350	3^	INFEC	Sinusitis/ sinus infection	1	01OCT2020	15/3	1	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1096 10961362	3^	INJ&P	Meniscus injury/ left meniscus tear	1	19SEP2020	3/C	2	No	O	NA	N	N/N
16-55/ C459100 1 1096 10961375	3^	GENRL	Injection site pain/ Site injection pain	1	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1096 10961376	3^	GENRL	Injection site pain/ Injection site soreness	1	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1096 10961378	3^	GENRL	Injection site pruritus/ Injection site pruritus	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
			Injection site swelling/ Injection site swelling	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
			Injection site pain/ Injection site soreness	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
			Fatigue/ Fatigue	1	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
			Fatigue/ FATIGUE	2	30OCT2020	1/3	2	Yes		NA	R (01NOV2020)	N/N
			Injection site pain/ INJECTION SITE PAIN IN LEFT ARM	2	30OCT2020	1/C	2	Yes		NA	N	N/N
			Pyrexia/ FEVER	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C459100 1 1096 10961382	3^	GENRL	Myalgia/ GENERALIZED MUSCLE ACHES	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
			Diarrhoea/ DIARRHEA	2	01NOV2020	3/C	1	Yes		NA	N	N/N
			Injection site pain/ Injection site soreness	1	09OCT2020	1/1	1	Yes		NA	R (09OCT2020)	N/Y
16-55/ C459100	3^	GENRL	Chills/ CHILLS	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11096 10961385			Fatigue/ FATIGUE	1	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	1	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
			Pain/ BODY ACHES	1	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
			Pyrexia/ FEVER	1	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	31OCT2020	2/C	2	Yes		NA	N	N/N
			Pyrexia/ FEVER	2	31OCT2020	2/C	1	Yes		NA	N	N/N
16-55/ C459100 11098 10981025	3^	RESP	Dry throat/ Dry Throat	1	29AUG2020	9/1	1	No	O	NA	R (29AUG2020)	N/N
16-55/ C459100 11098 10981054	3^	GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11098 10981101	3^	GENRL	Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1098 10981137		GENRL	Asthenia/ Weakness	1	12SEP2020	3/1	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1098 10981140	3^	GENRL	Pain/ Bodyache	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1098 10981141	3^	GENRL	Pain/ Bodyache	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1098 10981152	3^	GENRL	Chills/ Chills	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
			Pain/ Bodyache	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
			Pyrexia/ Fever	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1098 10981161	3^	MUSC	Back pain/ BackPain	1	20SEP2020	7/1	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C459100 1 1098 10981163	3^	GENRL	Chills/ Chills	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1098 10981176	3^	GASTR	Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
			Nausea/ Nausea	1	30SEP2020	15/1	1	Yes		NA/TC	R (30SEP2020)	N/N
		MUSC	Myalgia/ Muscle Pain	1	30SEP2020	15/1	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1098 10981177	3^	INV	Body temperature increased/ Elevated Temperature	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1098 10981180	3^	GENRL	Chills/ Chills	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1098 10981183	3^	GENRL	Pyrexia/ Fever	1	16SEP2020	1/4	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1098 10981188	3^	GENRL	Pyrexia/ Fever	1	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1098 10981207	3^	GENRL	Injection site pain/ Left injection site pain	1	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N
			Pyrexia/ Fever	1	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1098 10981217	3^	GENRL	Chills/ Chills	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
			Injection site pain/ Left arm injection site pain	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
		INV	Body temperature increased/ Elevated Temperature	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
		GENRL	Pyrexia/ Fever	2	14OCT2020	3/1	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1098 10981229	3^	GENRL	Pyrexia/ Fever	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Pain/ Bodyache	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
			Pyrexia/ Fever	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
		GENRL	Chills/ Chills	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C459100	3^		Injection site pain/ Injection site Pain	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
			Pain/ Bodyaches	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
			Pyrexia/ Fever	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
		GENRL	Chills/ Chills	1	03OCT2020	2/4	1	Yes		NA/TC	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11098 10981243			Pyrexia/ Fever	1	03OCT2020	2/4	1	Yes		NA/TC	R (06OCT2020)	N/N
		MUSC	Myalgia/ Muscle Ache	1	03OCT2020	2/4	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100 11101 11011004	3^	GENRL	Injection site erythema/ injection site redness	1	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N
			Injection site pain/ arm soreness in injection arm	1	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N
			Injection site pain/ pain at the injection site	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
			Pyrexia/ fever	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		NERV	Headache/ headache	1	02SEP2020	2/2	2	Yes		NA/TC	R (03SEP2020)	N/N
		GASTR	Nausea/ nausea	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
			Pyrexia/ fever	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ pain at injection site	1	03SEP2020	1/2	2	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11101 11011012		GENRL	Injection site pain/ pain at injection site	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 11101 11011013	3^	GENRL	Injection site warmth/ injection site warmth	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		NERV	Headache/ headache	1	04SEP2020	2/1	1	Yes		NA/TC	R (04SEP2020)	N/N
16-55/ C459100 11101 11011030	3^	GENRL	Pyrexia/ fever	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		RESP	Cough/ cough	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
			Upper respiratory tract congestion/ head congestion	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 11101 11011033	3^	GENRL	Chills/ chills	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
			Injection site pain/ injection site pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
			Pyrexia/ fever	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ chills	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1101 11011034		METAB	Injection site pain/ pain at injection site	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
			Decreased appetite/ decreased appetite	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
			Headache/ headache	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
			Nausea/ nausea	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Chills/ chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Headache/ headache	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1101 11011039	3^	GENRL	Injection site pain/ injection site pain	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
			Injection site pain/ injection site pain	2	02OCT2020	2/1	2	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1101 11011045	3^	GENRL	Injection site pain/ injection site pain	1	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
			Injection site pain/ injection site pain	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11101 11011048	3^	GENRL	Pyrexia/ fever	2	05OCT2020	1/3	2	Yes		NA/TC	R (07OCT2020)	N/N
		MUSC	Muscle fatigue/ muscle fatigue	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
		RESP	Oropharyngeal pain/ sore throat	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
			Sinus congestion/ sinus congestion	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 11101 11011052	3^	GENRL	Pyrexia/ fever	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 11101 11011056	3^	GENRL	Chills/ chills	1	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 11101 11011059	3^	GASTR	Diarrhoea/ diarrhea	1	17SEP2020	3/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11101 11011060	3^	INFEC	Gastroenteritis/ GASTROENTERITIS	1	18SEP2020	4/1	1	No	O	NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		REPRO	Adenomyosis/ adenomyosis	2	16OCT2020	11/C	2	No	O	NA	N	N/N
16-55/ C459100 11101 11011061	3^	GASTR	Nausea/ nausea	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 11101 11011062	3^	EYE	Eye pain/ bilateral eye soreness	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	08OCT2020	2/8	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ muscle aches	2	08OCT2020	2/3	2	Yes		NA/TC	R (10OCT2020)	N/N
		NERV	Headache/ headache	2	08OCT2020	2/3	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 11101 11011067	3^	GASTR	Diarrhoea/ diarrhea	2	14OCT2020	8/1	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C459100 11101 11011069	3^	INJ&P	Road traffic accident/ motor vehicle accident/subject was the driver	2	19OCT2020	11/1	2	No	O	NA	R (19OCT2020)	N/N
		MUSC	Myalgia/ muscle pain post-traumatic	2	19OCT2020	11/7	2	No	O	NA/TC	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11101 11011070	3^	GENRL	Injection site pain/ injection site pain	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 11101 11011072	3^	GENRL	Injection site pain/ injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11101 11011079	3^	GENRL	Injection site erythema/ injection site redness	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 11107 11071003	2^	GASTR	Tongue discomfort/ BURNT SENSATION ON TONGUE	1	11AUG2020	14/35	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C459100 11107 11071010	2^	INFEC	Vulvovaginal mycotic infection/ YEAST INFECTION VAGINAL	1	11AUG2020	13/7	1	No	O	NA/TC	R (17AUG2020)	N/N
16-55/ C459100 11107 11071015	3^	MUSC	Pain in extremity/ LEFT ARM PAIN	1	16AUG2020	14/8	1	Yes		NA	R (23AUG2020)	N/N
		GASTR	Haematochezia/ POSSIBLE BLOOD STREAKED STOOL	2	22SEP2020	28/C	1	No	O	NA	N	N/N
16-55/ C459100	3^	MUSC	Muscle twitching/ LEFT LOWER LIP TWITCH	1	06AUG2020	1/5	1	Yes		NA	R (10AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11107 11071054 16-55/ C459100	3^	BLOOD	Anaemia/ ANEMIA	2	09NOV2020	75/C	3	No	O	NA/TC/TCN	N	Y/N
11107 11071065 16-55/ C459100	3^	MUSC	Neck pain/ CERVICALGIA	1	29AUG2020	17/32	1	No	O	NA/TC	R (29SEP2020)	N/N
11107 11071112 16-55/ C459100	3^	GENRL	Chills/ CHILLLS	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N
11107 11071123			Fatigue/ FATIGUE	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ FEVER	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11107 11071129	3^	GASTR	Nausea/ NAUSEA	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
		RESP	Dyspnoea/ SHORTNESS OF BREATH	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C459100	3^	INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	1	31AUG2020	14/23	1	No	O	NA/TC	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11107 11071134 16-55/ C459100	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
11107 11071146 16-55/ C459100	3^	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE LEFT ARM	1	20AUG2020	1/3	1	Yes		NA/TC	R (22AUG2020)	N/N
11107 11071156		GENRL	Fatigue/ FATIGUE	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
			Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	2	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 11107 11071171	3^	REPRO	Prostatitis/ ACUTE PROSTATITIS	1	11SEP2020	18/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 11107 11071193	3^	RESP	Nasal congestion/ NASAL CONGESTION	1	15SEP2020	14/11	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C459100 11107 11071195	3^	INJ&P	Muscle rupture/ PARTIAL TEAR-LEFT CALF MUSCLE	1	16SEP2020	14/38	1	No	O	NA/TC	R (23OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11107 11071200	3 [^]	GENRL	Chills/ CHILLS	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
			Injection site pain/ LEFT ARM PAIN (INJECTION PAIN)	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 11107 11071204	3 [^]	GENRL	Chills/ CHILLS	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
			Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	1	08SEP2020	1/3	2	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 11109 11091002	2 [^]	GENRL	Injection site pain/ Injection site tenderness	1	29JUL2020	1/1	1	Yes		NA	R (29JUL2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11109 11091010	2^	GENRL	Injection site pain/ injection site tenderness	1	29JUL2020	1/3	2	Yes		NA/TC	R (31JUL2020)	N/N
16-55/ C459100 11109 11091016	2^	INJ&P	Contusion/ contusion of right hip	1	13AUG2020	15/C	1	No	O	NA	N	N/N
			Contusion/ contusion to pelvis	1	13AUG2020	15/C	1	No	O	NA	N	N/N
			Fall/ FALL FROM STEP	1	13AUG2020	15/1	1	No	O	NA	RS (13AUG2020)	N/N
16-55/ C459100 11109 11091030	2^	GENRL	Injection site erythema/ Injection Site Redness	1	30JUL2020	1/2	1	Yes		NA	R (31JUL2020)	N/N
16-55/ C459100 11109 11091080	3^	GENRL	Chills/ CHILLS	1	02AUG2020	2/1	1	Yes		NA	R (02AUG2020)	N/N
16-55/ C459100 11109 11091159	3^	MUSC	Myalgia/ LEFT ARM MYALGIA	1	04AUG2020	1/5	1	Yes		NA	R (08AUG2020)	N/N
16-55/ C459100 11109 11091204	3^	INFEC	Appendicitis/ ACUTE APPENDICITIS	1	17AUG2020	7/17	4	No	O	NA/TC	R (02SEP2020)	Y/N
			Peritoneal abscess/ Peritoneal Abscess	1	17AUG2020	7/17	4	No	O	NA/TC	R (02SEP2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11109 11091258	3^	SKIN	Dermatitis contact/ allergic contact dermatitis on all extremities and trunk	1	25AUG2020	10/16	2	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C459100 11109 11091320	3^	INV	Body temperature increased/ ELEVATED TEMPERATURE 102.0	1	24AUG2020	2/2	1	Yes		NA	R (25AUG2020)	N/N
16-55/ C459100 11109 11091331	3^	GENRL	Injection site pain/ INJECTION SITE PAIN LEFT ARM*		26AUG2020	1/3	2	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 11109 11091343	3^	NERV	Headache/ HEADACHE	1	29AUG2020	2/2	1	Yes		NA/TC/TCN	R (30AUG2020)	N/N
16-55/ C459100 11109 11091397	3^	EYE	Dry eye/ DRY EYES	1	09SEP2020	8/8	1	Yes		NA	R (16SEP2020)	N/N
		EYE	Dry eye/ DRY EYES	1	20SEP2020	19/18	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 11109 11091444	3^	GASTR	Diverticulum intestinal haemorrhagic/ BLOOD IN STOOL DIVERTICULOSIS	2	10OCT2020	12/11	2	No	O	NA	R (20OCT2020)	N/N
16-55/ C459100 11109 11091448	3^	NERV	Hemiplegic migraine/ Hemiplegic Migraine	2	20OCT2020	23/C	4	No	O	NA/TC	RG	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11109 11091466	3^	MUSC	Muscle spasms/ muscle spasm upper right abdomen	2	19OCT2020	20/6	3	No	O	NA	R (24OCT2020)	N/N
16-55/ C459100 11109 11091473	3^	GENRL	Pyrexia/ FEVER 101F	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 11109 11091488	3^	EAR	Ear pain/ Earache(bilateral)	1	18SEP2020	9/11	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C459100 11109 11091557	3^	GENRL	Injection site pain/ Injection Site Pain	2	26OCT2020	3/1	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C459100 11110 11101002	3^	MUSC	Neck pain/ neck pain	1	06AUG2020	7/8	1	No	O	NA	R (13AUG2020)	N/N
16-55/ C459100 11110 11101013	3^	GENRL	Fatigue/ fatigue	1	07AUG2020	7/4	1	Yes		NA	R (10AUG2020)	N/N
16-55/ C459100 11110 11101020	3^	NERV	Headache/ Headache	1	07AUG2020	5/3	1	Yes		NA/TC	R (09AUG2020)	N/N
16-55/ C459100	3^	GASTR	Diarrhoea/ diarrhea	1	25AUG2020	23/1	1	No	O	NA	R (25AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1110 11101021	3^	GENRL	Fatigue/ FATIGUE	1	03AUG2020	1/10	2	Yes		NA	R (12AUG2020)	N/N
1 1110 11101027		GASTR	Diarrhoea/ DIARRHEA	1	04AUG2020	2/9	2	Yes		NA	R (12AUG2020)	N/N
		NERV	Headache/ HEADACHE	1	04AUG2020	2/9	2	Yes		NA/TCN	R (12AUG2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ PAIN AT SITE INJECTION	1	12AUG2020	7/4	1	No	O	NA	R (15AUG2020)	N/N
1 1110 11101045												
16-55/ C459100	3^	UNC	HYPERTENSION@@/ Hypertension	2	12NOV2020	78/C	2	No	O	NA/TC	N	N/N
1 1110 11101050												
16-55/ C459100	3^	METAB	Hypertriglyceridaemia/ HYPERTRIGLYCERIDEMIA	1	12AUG2020	6/C	1	No	O	NA	N	N/N
1 1110 11101059												
16-55/ C459100	3^	RESP	Rhinorrhoea/ runny nose	1	19AUG2020	10/8	1	No	O	NA	R (26AUG2020)	N/N
1 1110 11101064												
16-55/ C459100	3^	GASTR	Toothache/ toothache	2	28SEP2020	28/23	1	No	O	NA/TC	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1110 11101078	3^	INJ&P	Joint injury/ right knee injury	2	29SEP2020	29/C	1	No	O	NA/TC	RG	N/N
1 1110 11101082	3^	SKIN	Rash maculo-papular/ Maculopapular rash to abdomen, chest, back and upper arms	1	30AUG2020	18/3	1	No	O	NA/TC	R (01SEP2020)	N/N
1 1110 11101091		RESP	Rhinorrhoea/ Runny nose	2	08OCT2020	37/1	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C459100	3^	MUSC	Bursitis/ Bursitis of Left Foot	2	30SEP2020	22/C	2	No	O	NA/TC	RG	N/N
1 1110 11101117			Plantar fasciitis/ Left Plantar Fasciitis	2	30SEP2020	22/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100	3^	MUSC	Myalgia/ mild muscle pain	1	08SEP2020	12/9	1	Yes		NA/TC	R (16SEP2020)	N/N
1 1110 11101151		NERV	Headache/ Headache	2	19SEP2020	2/8	2	Yes		NA/TC	R (26SEP2020)	N/N
		EYE	Vitreous floaters/ Right eye visual floaters	2	14OCT2020	27/10	2	No	O	NA	R (23OCT2020)	N/N
		NERV	Headache/ Headache	2	14OCT2020	27/13	1	No	O	NA/TC	R (26OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11110 11101167	3^	GASTR	Dental caries/ dental cavity	1	04SEP2020	7/1	2	No	O	NA/TC	R (04SEP2020)	N/N
16-55/ C459100 11110 11101189	3^	RESP	Oropharyngeal pain/ sore throat	1	15SEP2020	5/2	1	No	O	NA	R (16SEP2020)	N/N
16-55/ C459100 11110 11101220	3^	BLOOD	Lymphadenopathy/ Bilateral axillary adenopathy	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 11110 11101236	3^	SKIN	Rash/ rash to legs	2	08OCT2020	7/C	1	No	O	NA	N	N/N
		MUSC	Back pain/ back pain	2	31OCT2020	30/9	1	No	O	NA/TC	R (08NOV2020)	N/N
		UNC	BILATERAL EYE ITCHINESS@@/ Bilateral Eye Itchiness	2	14NOV2020	44/C	1	No	O	NA	N	N/N
			BILATERAL EYE REDNESS@@/ Bilateral Eye redness	2	14NOV2020	44/C	1	No	O	NA	N	N/N
			FATIGUE@@/ Fatigue	2	14NOV2020	44/C	1	No	O	NA	N	N/N
			THROAT ITCHINESS@@/ Throat Itchiness	2	14NOV2020	44/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11110 11101237	3^	GENRL	Injection site pain/ MILD INJECTION PAIN	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 11110 11101246	3^	GENRL	Injection site pain/ Pain at injection site left deltoid	1	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
			Malaise/ malaise	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 11110 11101269	3^	GENRL	Chills/ chills	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 11110 11101282	3^	BLOOD	Iron deficiency anaemia/ iron deficiency anemia	1	02OCT2020	12/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 11110 11101294	3^	GASTR	Dental caries/ Toothache (Dental Cavity)	1	01OCT2020	9/1	2	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C459100 11110 11101313	3^	GENRL	Injection site pain/ Pain at site injection	1	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
		NERV	Headache/ headache	1	01OCT2020	4/2	2	No	O	NA/TC	R (02OCT2020)	N/N
16-55/ C459100	3^	BLOOD	Lymphadenopathy/ Lymphadenopathy to left neck	2	21OCT2020	2/C	1	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1110 11101321		BLOOD	Neutropenia/ Neutropenia	2	26OCT2020	7/C	3	Yes		NA	N	N/N
16-55/ C459100 1 1110 11101323	3^	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	30OCT2020	11/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1110 11101337	3^	GASTR	Irritable bowel syndrome/ Irritable Bowel Syndrome	2	02NOV2020	12/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1110 11101338	3^	GENRL	Chills/ chills	2	22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C459100 1 1110 11101343	3^	GENRL	Chills/ Chills	2	27OCT2020	1/5	2	Yes		NA	R (31OCT2020)	N/N
			Pyrexia/ Fever	2	27OCT2020	1/5	2	Yes		NA/TC	R (31OCT2020)	N/N
		RESP	Cough/ Cough	2	27OCT2020	1/18	1	No	O	NA	R (13NOV2020)	N/N
16-55/ C459100 1 1111 11111099	3^	SKIN	Angioedema/ ANGIO-EDEMA BOTH EYES	1	23AUG2020	13/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11111 11111115	3^	NERV	Headache/ headache	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N
16-55/ C459100 11111 11111130	3^	NERV	Subarachnoid haemorrhage/ Subarachnoid hemorrhage	1	26AUG2020	9/9	2	No	O	NA/TC/TCN	R (03SEP2020)	Y/N
16-55/ C459100 11111 11111169	3^	RESP	Dyspnoea/ Air Huunger	1	02SEP2020	1/2	2	No	CD	NA/TC	R (03SEP2020)	N/N
16-55/ C459100 11111 11111176	3^	SKIN	Rash/ Rash on right side of neck	1	14SEP2020	7/21	2	No	CD	NA/TC	R (04OCT2020)	N/N
16-55/ C459100 11112 11121021	3^	PSYCH	Anxiety/ Worsening of anxiety	1	20AUG2020	21/35	2	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C459100 11112 11121047	3^	INJ&P	Hand fracture/ Broken finger, left middle finger	1	12AUG2020	10/21	3	No	O	NA/TC	R (01SEP2020)	N/N
16-55/ C459100 11112 11121071	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	10AUG2020	6/13	1	No	O	NA/TC	R (22AUG2020)	N/N
16-55/ C459100	3^	INFEC	Pharyngitis streptococcal/ Strep Throat	1	24AUG2020	20/12	1	No	O	NA/TC	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1112 11121078 16-55/ C459100	3^	VASC	Haematoma/ Hematoma	1	12AUG2020	3/12	1	No	O	NA/TC	R (23AUG2020)	N/N
1 1112 11121087 16-55/ C459100	3^	MUSC	Pain in extremity/ Leg pain	2	06SEP2020	7/1	1	No	O	NA/TC	R (06SEP2020)	N/N
1 1112 11121091 16-55/ C459100	3^	SKIN	Dermatitis contact/ Allergic reaction to poison ivy	1	25AUG2020	16/10	2	No	O	NA/TC	R (03SEP2020)	N/N
1 1112 11121101 16-55/ C459100	3^	MUSC	Bursitis/ Bursitis, left shoulder	2	22OCT2020	21/19	2	No	O	NA/TC	R (09NOV2020)	N/N
1 1112 11121125 16-55/ C459100	3^	INFEC	Tinea infection/ Ringworm	1	19AUG2020	3/31	2	No	O	NA/TC	R (18SEP2020)	N/N
1 1112 11121156 16-55/ C459100	3^	GENRL	Injection site paraesthesia/ Paresthesia, injection site, left arm	2	14SEP2020	4/2	2	Yes		NA	R (15SEP2020)	N/N
1 1112 11121173 16-55/ C459100	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	2	09OCT2020	25/6	3	No	O	NA/TC	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11112 11121183	3^	GENRL	Injection site pain/ Injection site Pain	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 11112 11121184	3^	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux disease	2	29SEP2020	15/38	3	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C459100 11112 11121188	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	13SEP2020	18/4	1	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C459100 11112 11121190	3^	GENRL	Chills/ Chills	2	17SEP2020	2/2	2	Yes		NA/TC/TCN	R (18SEP2020)	N/N
			Pyrexia/ Fever	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 11112 11121191	3^	GENRL	Injection site pain/ Injection site pain	1	29AUG2020	2/4	2	Yes		NA	R (01SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	1	29AUG2020	2/4	2	Yes		NA/TC	RS (01SEP2020)	N/N
16-55/ C459100 11112 11121193	3^	BLOOD	Lymph node pain/ Lymph node pain, under left arm	2	18SEP2020	2/5	3	Yes		NA/TC	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Lymphadenopathy/ Lymph node swelling (under left arm)	2	18SEP2020	2/6	3	Yes		NA/TC	R (23SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	18SEP2020	2/5	3	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 11112 11121194	3^	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 11112 11121197	3^	GENRL	Vaccination site pain/ Injection site pain, post vaccine	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C459100 11112 11121198	3^	GASTR	Diarrhoea/ Diarrhea, post vaccination	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain, post vaccination	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches, post vaccination	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C459100 11112 11121200	3^	GENRL	Fatigue/ Fatigue	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
			Injection site erythema/ Redness at injection site	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 11112 11121204	3^	GENRL	Injection site pain/ Injection site pain	1	01SEP2020	2/3	1	Yes		NA/TC	R (03SEP2020)	N/N	
			NERV	Headache/ Headache	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
			GENRL	Fatigue/ Fatigue	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
			MUSC	Myalgia/ Myalgia	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
			GENRL	Injection site pain/ Injection site soreness, left arm, post vaccine	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
			NERV	Headache/ Headache	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N
			GENRL	Injection site pain/ Injection site pain	2	24SEP2020	2/3	2	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 11112 11121208	3^	GENRL	Pain/ Pain, left side neck and upper arm	2	30SEP2020	8/13	2	Yes		NA/TC	R (12OCT2020)	N/N	
			MUSC	Myalgia/ Muscle aches(all over)	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 11112 11121214	3^	GENRL	Peripheral swelling/ Arm swelling, left arm	2	28SEP2020	5/3	2	Yes		NA/TC	R (30SEP2020)	N/N	
16-55/ C459100	3^	MUSC	Myalgia/ Muscle aches, post vaccine	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1112 11121215	3^	GENRL	Injection site pain/ Injection site pain, post vaccination	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
1 1112 11121216	3^	GENRL	Chills/ Chills	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
1 1112 11121226		MUSC	Myalgia/ Muscle Pain	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100 1 1112 11121237	3^	GENRL	Injection site pain/ Injection site pain (post vaccination)	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1112 11121242	3^	MUSC	Myalgia/ Muscle aches	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1112 11121249	3^	GENRL	Injection site pain/ Injection site pain, post vaccination	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1112 11121254		NERV	Headache/ Headache	1	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		NERV	Headache/ Headache	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
16-55/ C459100 1 1112 11121256	3^	GASTR	Diarrhoea/ Mild Diarrhea	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	07OCT2020	2/8	2	Yes		NA/TC	RS (14OCT2020)	N/N
			Injection site swelling/ Injection site swelling	1	07OCT2020	2/C	2	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1112 11121269	3^	MUSC	Myalgia/ Muscle Aches	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1112 11121282	3^	GENRL	Fatigue/ Fatigue	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		MUSC	Myalgia/ Muscle Aches	1	09OCT2020	1/2	2	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11114 11141041	3^	NERV	Headache/ exacerbation of headaches	1	25AUG2020	8/3	1	No	O	NA	R (27AUG2020)	N/N
16-55/ C459100 11114 11141065	3^	SKIN	Dermatitis contact/ Poison Ivy Rash Back	1	07SEP2020	19/8	1	No	O	NA	R (14SEP2020)	N/N
16-55/ C459100 11116 11161023	3^	INFEC	Cellulitis/ Cellulitis	2	18OCT2020	31/12	1	No	O	NA/TC	R (29OCT2020)	N/N
16-55/ C459100 11116 11161047	3^	NERV	Headache/ Headaches	1	01SEP2020	5/25	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C459100 11116 11161059	3^	GASTR	Obstructive pancreatitis/ Gall Stone Pancreatitis	1	13SEP2020	14/6	3	No	O	NA/TC/TCN	R (18SEP2020)	Y/N
		HEPAT	Bile duct stone/ Cholelithiasis	1	13SEP2020	14/7	3	No	O	NA/TC/TCN	R (19SEP2020)	Y/N
		CARD	Sinus arrhythmia/ Sinus Ahythmia	1	14SEP2020	15/C	1	No	O	NA	N	N/N
16-55/ C459100 11116 11161083	3^	GASTR	Abdominal hernia/ Upper Abdominal Hernia	1	SEP2020	1/	1	No	O	NA/TCN	R (21OCT2020)	N/N
			Umbilical hernia/ Umbilical Hernia	1	SEP2020	1/	1	No	O	NA/TCN	R (21OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11116 11161099	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	2	18OCT2020	24/12	1	No	O	NA/TC	R (29OCT2020)	N/N
16-55/ C459100 11116 11161115	3^	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 11116 11161200	3^	GENRL	Chills/ Chills	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Fatigue/ Fatigue	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Pain/ Body Aches	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ Pain @ Injection Site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/Y
		MUSC	Arthralgia/ Joint Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Myalgia/ Muscle Pains	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11116 11161204	3^	MUSC	Tenosynovitis stenosaurs/ DeQuervain's Tendinosis	1	24SEP2020	14/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 11116 11161228	3^	NERV	Presyncope/ Presyncope during blood draw	2	06NOV2020	30/1	1	No	O	NA	R (06NOV2020)	N/N
16-55/ C459100 11116 11161252	3^	GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
			Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 11116 11161276	3^	GENRL	Injection site mass/ Knot at Injection Site	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 11116 11161310	3^	IMMUN	Drug hypersensitivity/ allergic reaction to concomitant medication	2	18OCT2020	3/2	1	No	CD	NA	R (19OCT2020)	N/N
16-55/ C459100 11116 11161320	3^	PSYCH	Anxiety/ Anxiety	1	01OCT2020	7/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100	3^	MUSC	Rhabdomyolysis/ RHABDOMYOLYSIS	1	26AUG2020	7/5	1	No	O	NA/TC	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1117 11171036		NERV	Syncope/ Syncope Episode	1	26AUG2020	7/5	4	No	O	NA	R (30AUG2020)	Y/N
		RENAL	Acute kidney injury/ ACUTE KIDNEY INJURY	1	26AUG2020	7/5	1	No	O	NA/TC	R (30AUG2020)	N/N
		PSYCH	Suicidal ideation/ Suicidal ideation	1	27AUG2020	8/4	4	No	O	NA/TC	R (30AUG2020)	Y/N
		MUSC	Musculoskeletal stiffness/ NECK STIFFNESS	2	21SEP2020	12/C	1	No	O	NA	RG	N/N
		MUSC	Pain in extremity/ ARM SORENESS, LEFT	2	22SEP2020	13/11	2	No	O	NA	R (02OCT2020)	N/N
16-55/ C459100 1 1117 11171058	3^	BLOOD	Lymphadenopathy/ SUPRACLAVICULAR LYMPHADENOPATHY, RIGHT*		25AUG2020	1/C	1	No	O	NA	N	N/N
		NERV	Headache/ Headache	1	27AUG2020	3/3	1	Yes		NA/TC	R (29AUG2020)	N/N
16-55/ C459100 1 1117 11171070	3^	SKIN	Rash maculo-papular/ Maculopapular Rash, Generalized	1	07SEP2020	13/19	2	No	O	NA	R (25SEP2020)	N/N
		INJ&P	Skin laceration/ Laceration, Left Thumb	1	09SEP2020	15/21	2	No	O	NA/TC/TCN	R (29SEP2020)	N/N
16-55/ C459100 1 1117 11171100	3^	NERV	Headache/ HEADACHE	1	11SEP2020	8/4	2	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11117 11171102	3^	PSYCH	Attention deficit hyperactivity disorder/ ADHD	1	17SEP2020	14/C	1	No	CD	NA/TC	N	N/N
16-55/ C459100 11117 11171121	3^	SKIN	Angioedema/ ANGIOEDEMA	2	31OCT2020	26/4	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C459100 11117 11171156	3^	VASC	Hypertension/ HYPERTENSION*		24SEP2020	1/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 11117 11171186	3^	PSYCH	Depression/ DEPRESSION, WORSENING	1	19OCT2020	14/C	3	No	O	NA/TCN	N	N/N
			Suicide attempt/ SUICIDAL IDEATION WITH ATTEMPT	1	19OCT2020	14/8	3	No	O	NA/TC/TCN/ W	R (26OCT2020)	Y/N
		GASTR	Gastritis/ ACUTE GASTRITIS W/O HEMORRHAGE	1	23OCT2020	18/C	2	No	O	NA/TC/TCN	RG	N/N
			Vomiting/ BILIOUS VOMITING	1	23OCT2020	18/5	3	No	O	NA/TC/TCN	R (27OCT2020)	N/N
		GASTR	Abdominal pain/ ABDOMINAL PAIN	1	26OCT2020	21/2	2	No	O	NA/TC	R (27OCT2020)	N/N
16-55/ C459100 11117 11171187	3^	EAR	Tinnitus/ EAR RINGING, LEFT	2	27OCT2020	1/1	1	No	O	NA	R (27OCT2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11118 11181030	3^	MUSC	Muscle spasms/ back spasms	1	21AUG2020	8/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 11118 11181040	3^	INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2	12OCT2020	34/3	1	No	CD	NA/TC	R (14OCT2020)	N/N
16-55/ C459100 11118 11181100	3^	RENAL	Nephrolithiasis/ NEPHROLITHIASIS	2	25SEP2020	9/C	1	No	O	NA/TCN	RG	N/N
16-55/ C459100 11120 11201044	3^	GASTR	Diarrhoea/ Diarrhea	2	09SEP2020	15/1	1	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C459100 11120 11201103	3^	INFEC	Folliculitis/ folliculitis back of neck	2	26AUG2020	2/6	2	No	O	NA	R (31AUG2020)	N/N
16-55/ C459100 11120 11201104	3^	MUSC	Plantar fasciitis/ Worsening of plantar fasciitis	1	18AUG2020	13/6	1	No	O	NA/TC	R (23AUG2020)	N/N
16-55/ C459100 11120 11201148	3^	GENRL	Fatigue/ Fatigue	1	15AUG2020	4/2	3	Yes		NA	R (16AUG2020)	N/N
16-55/ C459100	3^	SKIN	Rash/ Rash torso and legs	1	27AUG2020	7/16	1	No	O	NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11120 11201250		NERV	Burning sensation/ Burning sensation in palm of left hand	2	16SEP2020	6/1	2	No	O	NA	R (16SEP2020)	N/N
16-55/ C459100 11120 11201299	3^	INFEC	Otitis media/ otitis media	1	06OCT2020	14/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100 11122 11221005	3^	GENRL	Chest pain/ chest aches	1	06SEP2020	4/26	1	Yes		NA	R (01OCT2020)	N/N
		MUSC	Arthralgia/ joint pain	1	07SEP2020	5/5	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Feeling hot/ sensation of hotness	2	26SEP2020	3/6	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11122 11221009	3^	NERV	Paraesthesia/ tingling of fingers in right hand	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/Y
16-55/ C459100 11122 11221012	3^	GENRL	Fatigue/ fatigue	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		METAB	Decreased appetite/ loss of appetite	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11122 11221014	3^	NERV	Headache/ headache	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
		GENRL	Chills/ Chills	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ fatigue	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
			Injection site pain/ injection site arm pain	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
			Pyrexia/ Fever	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
		GENRL	Fatigue/ fatigue, excessive	1	11SEP2020	3/4	1	Yes		NA	R (14SEP2020)	N/N
		GASTR	Gingival bleeding/ bleeding gums	2	01OCT2020	2/C	1	Yes		NA	N	N/N
			Loose tooth/ loose tooth	2	01OCT2020	2/C	1	Yes		NA	N	N/N
	GENRL	Fatigue/ fatigue	2	01OCT2020	2/C	1	Yes		NA	N	N/N	
	SKIN	Alopecia/ hair loss	2	01OCT2020	2/C	1	Yes		NA	N	N/N	
16-55/ C459100	3^	GENRL	Injection site paraesthesia/ tingling at injection site	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11122 11221016 16-55/ C459100	3^	GASTR	Diarrhoea/ Diarrhea	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
11122 11221024 16-55/ C459100		GENRL	Pain/ Body Aches	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
11122 11221025 16-55/ C459100	3^	INFEC	Oral herpes/ worsening of cold sore	1	15SEP2020	6/4	1	No	O	NA	R (18SEP2020)	N/N
11122 11221026 16-55/ C459100	3^	GASTR	Vomiting/ vomiting*		11SEP2020	/1	1	No	O	NA/W	R (11SEP2020)	N/N
		NERV	Presyncope/ pre-syncope*		11SEP2020	/1	1	No	O	NA/W	R (11SEP2020)	N/N
11122 11221028 16-55/ C459100	3^	GENRL	Fatigue/ fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
			Injection site pain/ injection site pain	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
			Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		MUSC	Arthralgia/ joint soreness at the shoulders	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11122 11221030	3^	GENRL	Malaise/ Malaise	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
			Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 11122 11221032	3^	NERV	Dizziness/ Dizziness (Loss of Balance)	1	28SEP2020	15/5	2	No	CD	NA	R (02OCT2020)	N/N
16-55/ C459100 11122 11221045	3^	GENRL	Injection site pain/ pain at injection site	2	28OCT2020	1/1	1	Yes		NA	R (28OCT2020)	N/Y
		NERV	Hypoaesthesia/ numbness in hand of injection arm	2	28OCT2020	1/1	1	Yes		NA	R (28OCT2020)	N/Y
			Paraesthesia/ tingling sensation in injection arm	2	28OCT2020	1/1	1	Yes		NA	R (28OCT2020)	N/Y
16-55/ C459100 11122 11221052	3^	GENRL	Non-cardiac chest pain/ Acute Illness non cardiac chest pain	1	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
16-55/ C459100 11123 11231009	3^	REPRO	Dysmenorrhoea/ Worsening of dysmenorrhea	1	05AUG2020	7/13	1	No	O	NA/TC/TCN	R (17AUG2020)	N/N
		CONG	Congenital cystic kidney disease/ Polycystic kidney disease	1	17AUG2020	19/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11123 11231041	3^	GENRL	Fatigue/ FATIGUE	1	11AUG2020	7/2	1	Yes		NA	R (12AUG2020)	N/N
16-55/ C459100 11123 11231043	3^	GENRL	Fatigue/ FATIGUE	1	12AUG2020	7/3	1	No	O	NA	R (14AUG2020)	N/N
		SKIN	Erythema/ Mild erythema bilateral nares	2	25AUG2020	1/C	1	No	O	NA	N	N/N
16-55/ C459100 11123 11231064	3^	GASTR	Hiatus hernia/ hiatal hernia	1	13AUG2020	4/C	1	No	O	NA/TCN	N	N/N
16-55/ C459100 11123 11231074	3^	MUSC	Myalgia/ myalgia	1	16AUG2020	6/4	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C459100 11123 11231086	3^	GENRL	Fatigue/ Fatigue	2	04SEP2020	4/6	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 11123 11231094	3^	GENRL	Fatigue/ FATIGUE	1	14AUG2020	2/8	1	No	O	NA	R (21AUG2020)	N/N
		MUSC	Arthralgia/ JOINT PAIN	1	19AUG2020	7/3	1	No	O	NA	R (21AUG2020)	N/N
16-55/ C459100	3^	NEOPL	Lipoma/ Right axilla lipoma	2	23SEP2020	16/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11123 11231114	3^	GENRL	Pyrexia/ Fever	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
11123 11231116	3^	MUSC	Periarthritis/ Worsening of right adhesive capsulitis shoulder	2	14SEP2020	7/23	1	No	O	NA/TC	R (06OCT2020)	N/N
11123 11231117	3^	GENRL	Chills/ CHILLS	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
			Pyrexia/ FEVER	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
		MUSC	Myalgia/ FULL BODY MYALGIA	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
11123 11231128	3^	GENRL	Pyrexia/ Fever	2	09SEP2020	2/2	1	Yes		NA/TC	R (10SEP2020)	N/N
11123 11231143	3^	MUSC	Myalgia/ Full body myalgia	2	12SEP2020	3/2	1	No	O	NA/TC	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INFEC	Pharyngitis streptococcal/ Strep pharyngitis	2	06NOV2020	58/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 11123 11231176	3^	GENRL	Injection site pain/ Pain at injection site, left arm	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 11123 11231187	3^	GENRL	Pyrexia/ Fever	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		NERV	Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 11123 11231197	3^	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 11123 11231208	3^	INJ&P	Fall/ Fall	1	18SEP2020	22/1	2	No	O	NA	R (18SEP2020)	N/N
			Foot fracture/ Left foot fracture	1	18SEP2020	22/12	1	No	O	NA/TC/TCN	R (29SEP2020)	N/N
16-55/ C459100 11123 11231216	3^	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11123 11231217	3^	GENRL	Pyrexia/ Fever	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
			Myalgia/ Full body myalgia	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
			Headache/ Headache	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
			Chills/ Chills	2	28SEP2020	1/C	1	Yes		NA/TC	N	N/N
			Arthralgia/ joint pain	2	28SEP2020	1/C	1	Yes		NA/TC	N	N/N
			Myalgia/ Full body myalgia	2	28SEP2020	1/C	1	Yes		NA/TC	N	N/N
16-55/ C459100 11123 11231233	3^	GENRL	Dizziness/ Dizziness	2	28SEP2020	1/C	1	Yes		NA	N	N/N
			Injection site pain/ Injection site pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
			Arthralgia/ Joint pain	1	13SEP2020	4/3	1	Yes		NA/TC	R (15SEP2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100	3^	GASTR	Myalgia/ Myalgia	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
			Teething/ Wisdom tooth eruption with pain	1	30SEP2020	20/22	1	No	O	NA/TC	R (21OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11123 11231237	3^	GENRL	Injection site pain/ Pain at injection site	1	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
11123 11231252	3^	GASTR	Diarrhoea/ Diarrhea	2	08OCT2020	3/3	1	Yes		NA	R (10OCT2020)	N/N
11123 11231264		GENRL	Chills/ Chills	2	08OCT2020	3/1	1	Yes		NA	R (08OCT2020)	N/N
			Pyrexia/ Fever	2	08OCT2020	3/1	1	Yes		NA/TC	R (08OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	08OCT2020	3/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 11123 11231289	3^	GENRL	Chills/ Chills	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ Injection site pain	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ Headache	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
		GASTR	Nausea/ nausea	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
		GENRL	Chills/ Chills	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1123 11231294	3^	NERV	Malaise/ malaise	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
			Headache/ Headache	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
			Injection site pain/ Pain at injection site	2	15OCT2020	2/3	1	Yes		NA	R (17OCT2020)	N/N
		NERV	Headache/ Headache	1	29SEP2020	7/2	1	No	O	NA/TC	R (30SEP2020)	N/N
		GENRL	Chills/ Chills	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
		MUSC	Fatigue/ Fatigue	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1123 11231307	3^	GENRL	Myalgia/ Myalgia	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
			Pyrexia/ Fever	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1123 11231313	3^	NERV	Headache/ Headache	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
			Headache/ Headache	1	06OCT2020	13/2	1	No	O	NA/TC	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11123 11231317	3^	PSYCH	Bruxism/ Bruxism	2	27OCT2020	14/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 11123 11231322	3^	GASTR	Haemorrhoids/ Hemorrhoids	1	04OCT2020	10/5	1	No	O	NA/TC	R (08OCT2020)	N/N
16-55/ C459100 11123 11231327	3^	INFEC	Vulvovaginal candidiasis/ Vulvovaginal candidiasis	1	02OCT2020	8/4	1	No	O	NA/TC	R (05OCT2020)	N/N
		INFEC	Acute sinusitis/ Acute sinusitis	2	30OCT2020	17/7	1	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C459100 11123 11231328	3^	MUSC	Myalgia/ FULL BODY MYALGIA	1	26SEP2020	2/3	1	Yes		NA/TC	R (28SEP2020)	N/N
16-55/ C459100 11123 11231334	3^	INFEC	Cystitis/ Acute cystitis	1	01OCT2020	7/5	1	No	O	NA/TC	R (05OCT2020)	N/N
16-55/ C459100 11123 11231338	3^	GENRL	Chills/ Chills	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/ Pain at injection site	1	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100	3^	MUSC	Myalgia/ Muscle pain	1	09OCT2020	2/C	1	Yes		NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11123 11231350 16-55/ C459100	3^	MUSC	Osteitis/ Inflamed first metatarsal	1	02SEP2020	24/36	2	No	O	NA/TC	R (07OCT2020)	N/N
11124 11241003 16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	28AUG2020	17/2	1	Yes		NA/TC	R (29AUG2020)	N/N
11124 11241026 16-55/ C459100	3^	INJ&P	Foot fracture/ Right foot fracture	1	01SEP2020	16/8	1	No	O	NA/TC	R (08SEP2020)	N/N
11124 11241042		INJ&P	Limb injury/ Left thumb injury	1	02SEP2020	17/1	1	No	O	NA/TCN	R (02SEP2020)	N/N
16-55/ C459100 11124 11241047	3^	GENRL	Vaccination site pain/ Muscle Soreness at vaccination site	2	13SEP2020	4/4	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 11124 11241049	3^	GENRL	Chills/ Chills	1	18AUG2020	2/C	2	Yes		NA	N	N/N
			Pyrexia/ Fever (101 degrees F)	1	18AUG2020	2/C	2	Yes		NA	N	N/N
		MUSC	Myalgia/ Muscle Pain	1	18AUG2020	2/C	2	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	1	18AUG2020	2/C	2	Yes		NA	N	N/N
16-55/ C459100 11124 11241053	3^	MUSC	Myalgia/ Myalgias	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
		NERV	Headache/ Headache	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 11124 11241058	3^	INFEC	Herpes zoster/ Shingles	2	04OCT2020	25/8	2	No	O	NA/TC	R (11OCT2020)	N/N
		MUSC	Rotator cuff syndrome/ Torn rotator cuff (right)	2	08OCT2020	29/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 11124 11241066	3^	INJ&P	Foot fracture/ Left foot fracture	1	07SEP2020	20/44	1	No	O	NA/TCN	R (20OCT2020)	N/N
16-55/ C459100 11124 11241071	3^	GENRL	Injection site pain/ Injection site soreness	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 11124 11241075	3^	GENRL	Chills/ Chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11124 11241083	3^	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/4	2	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 11124 11241084	3^	METAB	Hypokalaemia/ Hypokalemia (2.8)	1	01SEP2020	9/1	1	No	O	NA/TC	R (01SEP2020)	N/N
16-55/ C459100 11124 11241086	3^	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ Injection site pain	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 11124 11241094	3^	MUSC	Myalgia/ Myalgia	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11124 11241095	3^	GENRL	Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11124 11241099	3^	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11124 11241100	3^	MUSC	Myalgia/ Myalgias	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		INJ&P	Head injury/ Mild trauma to central forehead	1	12SEP2020	18/7	2	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C459100 11124 11241102	3^	GENRL	Injection site erythema/ Injection site erythema	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
		REPRO	Dysmenorrhoea/ Menstrual cramps	1	11SEP2020	17/4	1	No	O	NA/TC	R (14SEP2020)	N/N
16-55/ C459100 11124 11241106	3^	RESP	Nasal congestion/ Nasal Congestion	1	12SEP2020	18/6	1	No	O	NA/TC	R (17SEP2020)	N/N
			Oropharyngeal pain/ Sore Throat	1	12SEP2020	18/2	1	No	O	NA/TC	R (13SEP2020)	N/N
		NERV	Headache/ Headache	2	25SEP2020	12/4	2	No	O	NA/TC	R (28SEP2020)	N/N
			Lethargy/ Lethargy	2	25SEP2020	12/4	2	No	O	NA	R (28SEP2020)	N/N
		CARD	Acute myocardial infarction/ ST elevation myocardial infarction	2	27SEP2020	12/17	4	No	O	NA	R (13OCT2020)	Y/N
16-55/ C459100 11124 11241108	3^	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/5	2	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11124 11241113	3^	MUSC	Myalgia/ Myalgias	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
		NERV	Headache/ Worsening Headache	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 11124 11241118	3^	GENRL	Malaise/ Malaise	1	28AUG2020	2/3	2	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 11124 11241125	3^	INJ&P	Ligament sprain/ Right Ankle Sprain	2	07OCT2020	16/8	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C459100 11124 11241127	3^	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 11124 11241142	3^	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/1	2	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ Chills	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11124 11241149	3^	GENRL	Pyrexia/ Fever	2	25SEP2020	2/4	1	Yes		NA	R (28SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	25SEP2020	2/4	2	Yes		NA	R (28SEP2020)	N/N
16-55/ C459100 11124 11241152	3^	GENRL	Fatigue/ Fatigue	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ Injection site pain	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 11124 11241167	3^	INFEC	Urinary tract infection/ Suspected Urinary Tract Infection	1	20SEP2020	18/2	1	No	O	NA/TC	R (21SEP2020)	N/N
		NERV	Sciatic nerve neuropathy/ Left sided sciatic neuropathy	2	16OCT2020	25/C	2	No	O	NA	RG	N/N
16-55/ C459100 11124 11241170	3^	GENRL	Chills/ Chills	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
			Injection site pain/ Injection site soreness	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
			Malaise/ General Malaise	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11124 11241174	3^	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 11124 11241179	3^	NERV	Headache/ Headache	2	02OCT2020	4/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 11124 11241184	3^	MUSC	Myalgia/ Myalgias	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 11124 11241198	3^	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11124 11241200	3^	GENRL	Chills/ Chills	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
			Fatigue/ Fatigue	2	02OCT2020	1/4	2	Yes		NA	R (05OCT2020)	N/N
			Pyrexia/ Fever	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11124 11241202	3^	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 11124 11241207	3^	BLOOD	Lymphadenopathy/ Left axilla adenopathy	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
		GENRL	Pyrexia/ Fever	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		MUSC	Myalgia/ Myalgias	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 11124 11241213	3^	MUSC	Pain in extremity/ Bilateral hand soreness	1	13SEP2020	3/2	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness	2	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N
			Pyrexia/ Fever	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		MUSC	Joint stiffness/ Joint stiffness	2	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 11124 11241216	3^	GENRL	Injection site pain/ Injection site pain	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11124 11241218	3^	MUSC	Myalgia/ Myalgias	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 11124 11241219	3^	NERV	Headache/ Headache	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	02OCT2020	3/8	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 11124 11241222	3^	METAB	Decreased appetite/ Loss of appetite	2	02OCT2020	3/15	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 11124 11241223	3^	SKIN	Night sweats/ Increased diaphoresis during sleep	2	14OCT2020	8/C	1	No	O	NA	N	N/N
16-55/ C459100 11124 11241225	3^	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/5	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 11124 11241226	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/5	1	Yes		NA/TC	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11124 11241234	3^	GENRL	Injection site pain/ Injection site soreness	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Pyrexia/ Fever	1	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
		NERV	Headache/ Headache	1	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		NERV	Headache/ Headache	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 11124 11241235	3^	GENRL	Fatigue/ Fatigue	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 11125 11251021	3^	GENRL	Swelling/ under arm swelling left arm	1	18AUG2020	6/2	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C459100 11125 11251028	3^	INFEC	Sinusitis/ Sinus Infection	1	26AUG2020	14/5	1	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	23/4	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11125 11251044	3^	NERV	Headache/ headache	1	04SEP2020	15/2	1	Yes		NA	R (05SEP2020)	N/N
11125 11251067	3^	INFEC	Sinusitis/ Sinus infection	2	05OCT2020	22/16	1	No	O	NA/TC	R (20OCT2020)	N/N
11125 11251075	3^	INFEC	Upper respiratory tract infection/ upper respiratory infection	2	13OCT2020	30/8	1	No	O	NA	R (20OCT2020)	N/N
11125 11251087	3^	RESP	Oropharyngeal pain/ Sore throat	2	28SEP2020	15/1	1	No	O	NA	R (28SEP2020)	N/N
11125 11251106	3^	IMMUN	Seasonal allergy/ Acute exacerbation of seasonal allergies	2	18SEP2020	4/C	1	No	O	NA/TC	RG	N/N
11125 11251109	3^	GENRL	Pain/ Body Aches	1	08SEP2020	12/8	1	Yes		NA	R (15SEP2020)	N/N
11125 11251126	3^	RESP	Oropharyngeal pain/ Sore throat	2	25OCT2020	32/4	1	No	O	NA	R (28OCT2020)	N/N
11125 11251138												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11125 11251144	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	23SEP2020	22/5	1	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C459100 11125 11251174	3^	METAB	Hypocholesterolaemia/ Hypocholesterolemia	2	28SEP2020	6/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 11125 11251180	3^	GENRL	Fatigue/ fatigue	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N
			Pain/ bodyaches	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N
			Pyrexia/ Fever	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 11125 11251181	3^	REPRO	Ovarian cyst/ Right Ovarian Cyst	2	22OCT2020	24/C	2	No	O	NA	RG	N/N
16-55/ C459100 11125 11251182	3^	GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	8/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 11125 11251183	3^	GENRL	Pain/ bodyaches	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ injection site pain	2	01OCT2020	4/1	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1125 11251193												
16-55/ C459100 1 1125 11251201	3^	RESP	Nasal congestion/ Stuffy nose	2	15OCT2020	14/C	1	No	O	NA	N	N/N
			Oropharyngeal pain/ Sore throat	2	15OCT2020	14/3	1	No	O	NA	R (17OCT2020)	N/N
16-55/ C459100 1 1125 11251202	3^	GASTR	Peptic ulcer/ Peptic Ulcer	1	20SEP2020	11/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1125 11251207	3^	GENRL	Injection site pain/ Injection Site pain	1	14SEP2020	5/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1125 11251212	3^	NERV	Syncope/ syncopal episode during vasovagal response during venous puncture	2	03NOV2020	35/1	1	No	O	NA	R (03NOV2020)	N/N
16-55/ C459100 1 1126 11261006	3^	INFEC	Otitis media/ Left otitis media	1	16AUG2020	6/12	1	No	O	NA/TC	R (27AUG2020)	N/N
16-55/ C459100 1 1126 11261014	3^	NERV	Paraesthesia/ Generalized Body Tingling	1	12AUG2020	1/1	1	No	O	NA	R (12AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11126 11261017	3 [^]	SKIN	Urticaria/ Hives	1	12AUG2020	1/1	1	No	O	NA	R (12AUG2020)	N/N
		INFEC	Vulvovaginal candidiasis/ Candida of vagina	2	03SEP2020	2/4	1	No	O	NA/TC	R (06SEP2020)	N/N
		INFEC	Acute sinusitis/ Acute sinusitis	1	15AUG2020	3/6	1	No	O	NA/TC	R (20AUG2020)	N/N
16-55/ C459100 11126 11261018	3 [^]	INFEC	Diverticulitis/ Diverticulitis	1	28AUG2020	16/4	1	No	O	NA	R (31AUG2020)	N/N
16-55/ C459100 11126 11261029	3 [^]	GENRL	Injection site pain/ Pain, Injection site	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11126 11261034	3 [^]		Pain/ Bodyaches	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Headache	1	09SEP2020	24/2	2	Yes		NA	R (10SEP2020)	N/N
		GENRL	Non-cardiac chest pain/ Chest Pain, non-cardiac	2	28SEP2020	20/6	2	No	O	NA/TC	R (03OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
		MUSC	Myalgia/ Muscle Aches	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11126 11261041	3^	GENRL	Pain in extremity/ Left upper arm pain	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
			Chills/ Body Chills	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ Fatigue	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N	
		MUSC	Myalgia/ Muscle Pain	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
	IN FEC	Cellulitis/ Cellulitis, Right Thumb	2	10SEP2020	2/11	2	No	O	NA/TC	R (20SEP2020)	N/N	
	3^	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	2/4	2	Yes		NA	R (13SEP2020)	N/N
	3^	HEPAT	Cholelithiasis/ Cholelithiasis	1	30AUG2020	12/C	2	No	O	NA/TC	N	N/N
		MUSC	Arthralgia/ Shoulder pain, Right	1	30AUG2020	12/1	2	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C459100 11126 11261048	3^	IN FEC	Vulvovaginal candidiasis/ Candida of vagina	1	08SEP2020	20/C	1	No	O	NA	N	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/3	2	Yes		NA	R (12SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pain/ Body aches	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1126 11261053	3^	EAR	Cerumen impaction/ Bilateral Cerumen Impaction	1	07SEP2020	19/2	1	No	O	NA	R (08SEP2020)	N/N
16-55/ C459100 1 1126 11261055	3^	INJ&P	Fall/ Mechanical Fall	2	29SEP2020	20/1	2	No	O	NA	R (29SEP2020)	N/N
		MUSC	Musculoskeletal chest pain/ Chest wall pain, left	2	29SEP2020	20/25	2	No	O	NA	R (23OCT2020)	N/N
16-55/ C459100 1 1126 11261056	3^	GENRL	Injection site pain/ Pain, injection site	1	21AUG2020	1/2	2	Yes		NA	R (22AUG2020)	N/N
16-55/ C459100 1 1126 11261061	3^	MUSC	Pain in extremity/ Left upper arm pain	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
		MUSC	Pain in extremity/ Left upper arm pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
			Malaise/ Malaise	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100	3^	REPRO	Pelvic pain/ Pelvic pain	1	25AUG2020	5/4	2	No	O	NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1126 11261062		GENRL	Fatigue/ Fatigue	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
		NERV	Headache/ Headache	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		ENDO	Hypothyroidism/ Hypothyroidism	2	12SEP2020	3/C	2	No	O	NA	N	N/N
		INV	C-reactive protein/ C-reactive protein, 1.6mg/dl	2	12SEP2020	3/C	2	No	O	NA	N	N/N
		RESP	Sleep apnoea syndrome/ Sleep Apnea	2	14OCT2020	35/C	2	No	O	NA/TCN	N	N/N
16-55/ C459100 1 1126 11261064	3^	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
		MUSC	Pain in extremity/ Left upper arm pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C459100 1 1126 11261068	3^	PSYCH	Stress/ Stress	2	17SEP2020	3/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1126 11261076	3^	GENRL	Chills/ Chills	2	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11126 11261078	3^	MUSC	Fatigue/ Fatigue	2	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N
			Injection site pain/ Left upper arm injection site pain	2	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N
			Myalgia/ Muscle aches	2	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 11126 11261078	3^	MUSC	Pain in extremity/ Left upper arm pain	2	14SEP2020	1/3	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 11126 11261082	3^	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 11126 11261083	3^	GENRL	Pain/ Body aches	2	17SEP2020	1/3	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 11126 11261085	3^	GENRL	Pyrexia/ Fever, 101.2F	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
			Fatigue/ Fatigue	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N
			Pain in extremity/ Upper right arm pain	1	27AUG2020	1/4	1	Yes		NA/TC	R (30AUG2020)	N/N
		NERV	Headache/ Headache	1	27AUG2020	1/2	1	Yes		NA/TC	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1126 11261093	3^	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/4	2	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	16SEP2020	2/4	1	Yes		NA/TC	R (19SEP2020)	N/N
		NERV	Headache/ Headache	2	16SEP2020	2/4	2	Yes		NA/TC	R (19SEP2020)	N/N
		MUSC	Pain in extremity/ Left upper arm pain	1	28AUG2020	1/4	1	Yes		NA/TC	R (31AUG2020)	N/N
		MUSC	Myalgia/ Muscle aches	1	29AUG2020	2/3	1	Yes		NA/TC	R (31AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1126 11261101	3^		Malaise/ Malaise	2	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
			Pain/ Body aches	2	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Pain/ Body Aches	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1126 11261103	3^	GENRL	Injection site pain/ Pain, injection site	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11126 11261109	3^	GENRL	Chills/ Chills	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
			Pain/ Body Aches	2	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
			Injection site pain/ Injection site pain	2	22SEP2020	2/4	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 11126 11261111	3^	INFEC	Pain/ Body Aches	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			Urinary tract infection/ Urinary tract infection	2	18OCT2020	28/7	2	No	O	NA/TC	R (24OCT2020)	N/N
16-55/ C459100 11126 11261116	3^	NERV	Headache/ Headache	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C459100 11126 11261121	3^	GENRL	Injection site pain/ Pain injection site	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ Pain, Injection site	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
			Pain/ Generalized Body Aches	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11126 11261122	3^	NERV	Headache/ Headache	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		MUSC	Pain in extremity/ Left upper arm pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
		EAR	Vertigo/ Vertigo	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
			Nausea/ Nausea	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 11126 11261124	3^	NERV	Headache/ Headache	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	03SEP2020	2/3	2	Yes		NA	R (05SEP2020)	N/N
		MUSC	Pain in extremity/ Left upper arm pain	1	03SEP2020	2/5	2	Yes		NA/TC	R (07SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N
			Malaise/ Malaise	2	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11126 11261126	3^	INFEC	Urinary tract infection/ Urinary tract infection	2	20OCT2020	29/4	1	No	O	NA/TC	R (23OCT2020)	N/N
		GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ Injection site pain	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
			Pain/ Body Aches	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 11126 11261128	3^	NERV	Dizziness/ Dizziness	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ Fatigue*		03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
			Malaise/ Malaise*		03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 11126 11261134	3^	MUSC	Pain in extremity/ Left upper arm pain*		03SEP2020	1/3	2	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	25SEP2020	2/3	2	Yes		NA/TC	R (27SEP2020)	N/N
		GENRL	Pain/ Body aches, generalized	1	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N
		GENRL	Pain/ Body aches (generalized)	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11126 11261141	3 [^]	MUSC	Pain in extremity/ Right Foot Pain	1	14SEP2020	11/12	1	No	O	NA/TCN	R (25SEP2020)	N/N
16-55/ C459100 11126 11261142	3 [^]	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ Fever, 102.1F	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 11126 11261143	3 [^]	REPRO	Pelvic pain/ Acute Female Pelvic Pain	2	17OCT2020	20/8	2	No	O	NA/TC	R (24OCT2020)	N/N
16-55/ C459100 11126 11261148	3 [^]	GENRL	Injection site pain/ Injection site pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
			Pain/ Body aches	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100	3 [^]	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11126 11261150			Injection site pain/ Injection site pain	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
		EAR	Tinnitus/ Left Tinnitus	1	14SEP2020	6/6	1	No	O	NA	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ Injection site pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11126 11261151	3^	EYE	Conjunctivitis allergic/ Bilateral Allergic Conjunctivitis	1	11SEP2020	3/6	1	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C459100 11126 11261157	3^	MUSC	Pain in extremity/ Left upper arm pain	1	09SEP2020	1/3	2	Yes		NA/TC	R (11SEP2020)	N/N
		GENRL	Chills/ Chills	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Malaise/ Malaise	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	1	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	29SEP2020	2/3	2	Yes		NA/TC	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1126 11261158	3^	GENRL	Injection site pain/ Injection site pain	2	29SEP2020	2/4	2	Yes		NA/TC	R (02OCT2020)	N/N
			Pain/ Body Aches	2	29SEP2020	2/3	2	Yes		NA/TC	R (01OCT2020)	N/N
			Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
			Fatigue/ Fatigue	2	01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1126 11261166	3^	GENRL	Injection site pain/ Pain, Injection Site	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
			Chills/ Chills	1	01OCT2020	21/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		Fatigue/ Fatigue	1	01OCT2020	21/2	2	Yes		NA/TC	R (02OCT2020)	N/N	
		Injection site pain/ Injection site pain	1	01OCT2020	21/4	1	Yes		NA/TC	R (04OCT2020)	N/N	
		Injection site pain/ Pain, Injection site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N	
		Pain/ Body aches	1	01OCT2020	21/2	2	Yes		NA/TC	R (02OCT2020)	N/N	
		GENRL	Injection site pain/ Pain, injection site	1	11SEP2020	1/2	3	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	1	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Chills/ Body Chills	1	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ Fever	1	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
		MUSC	Neck pain/ Neck Pain	1	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Pain/ Body aches	2	30SEP2020	1/3	2	Yes		NA/TC	R (02OCT2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	1/3	2	Yes		NA/TC	R (02OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	1/3	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1126 11261172	3^	GENRL	Injection site pain/ Pain, injection site	1	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
		GENRL	Malaise/ Malaise	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
			Pyrexia/ Fever, 101.6F	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1126 11261173	3^	GENRL	Injection site pain/ Injection site pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ Fatigue	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
			Injection site pain/ Injection site pain	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
		MUSC	Arthralgia/ Joint Pain, Generalized	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
			Myalgia/ Muscle Pain, Generalized	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
		GENRL	Pyrexia/ Fever, 100F	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1126 11261178	3^	MUSC	Pain in extremity/ Left upper arm pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1126 11261182	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1126 11261183	3^	NERV	Headache/ Headache	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11126 11261185		NERV	Dizziness/ Dizzy Spell	1	21SEP2020	5/1	2	No	O	NA	R (21SEP2020)	N/N
16-55/ C459100 11126 11261186	3^	GENRL	Injection site pain/ Pain, injection site	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 11126 11261187	3^	GENRL	Fatigue/ Fatigue	1	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ Pain, Injection site	1	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
			Pain/ Body aches	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 11126 11261193	3^	GENRL	Injection site pain/ Pain, Injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		NERV	Headache/ Headache	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 11126 11261194	3^	NERV	Headache/ Headache	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ Pain, Injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		EAR	Vertigo/ Vertigo	2	06NOV2020	29/C	1	No	O	NA	RG	N/N
16-55/ C459100 11126 11261196	3^	MUSC	Myalgia/ Muscle Aches	2	13OCT2020	2/2	2	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 11126 11261197	3^	GENRL	Chills/ Chills	1	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
			Malaise/ Malaise	1	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	1	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
			Pain in extremity/ Left upper arm pain	1	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Headache/ Headache	1	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
			Injection site pain/ Left injection site arm pain	2	12OCT2020	1/3	1	Yes		NA/TC	R (14OCT2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N
		NERV	Headache/ Headache	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1126 11261199			Injection site pain/ Pain, Injection site	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
			Pyrexia/ Fever	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
		NERV	Headache/ Headache	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1127 11271015	2^	INFEC	Nasopharyngitis/ common cold	2	01OCT2020	45/4	1	No	O	NA	R (04OCT2020)	N/N
16-55/ C459100 1 1127 11271022	3^	MUSC	Arthralgia/ joint pain	1	31JUL2020	2/C	2	Yes		NA/TC	N	N/N
		NERV	Headache/ headache	1	03AUG2020	5/14	3	Yes		NA/TC	R (16AUG2020)	N/N
		INFEC	Sinusitis/ Sinus infection	1	04AUG2020	6/C	2	No	O	NA/TC	N	N/N
		PSYCH	Insomnia/ Insomnia	1	22AUG2020	24/C	1	No	O	NA/TC	N	N/N
			Schizophrenia/ Schizophrenia	1	22AUG2020	24/C	1	No	O	P/TC	N	N/N
		NERV	Headache/ Headache	1	15SEP2020	48/C	1	No	O	NA/TC	N	N/N
		GENRL	Influenza like illness/ Flu like symptoms	1	26SEP2020	59/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11127 11271026	3^	SKIN	Dermatitis contact/ Contact dermatitis (poison ivy)	2	26AUG2020	8/9	1	No	O	NA/TC	R (03SEP2020)	N/N
16-55/ C459100 11127 11271073	3^	PSYCH	Anxiety/ worsening of anxiety	2	02SEP2020	9/C	1	No	O	NA	N	N/N
			Depression/ worsening of depression	2	02SEP2020	9/C	1	No	O	NA	N	N/N
16-55/ C459100 11127 11271086	3^	GASTR	Dental caries/ Dental caries	2	04SEP2020	6/3	1	No	O	NA	R (06SEP2020)	N/N
			Toothache/ toothache	2	04SEP2020	6/3	1	No	O	NA/TC/TCN	R (06SEP2020)	N/N
16-55/ C459100 11127 11271097	3^	NERV	Sinus headache/ headache sinus	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 11128 11281005	3^	SKIN	Rash/ Rash upper torso	2	12SEP2020	25/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 11128 11281017	3^	INJ&P	Fall/ Fall	1	08AUG2020	8/1	2	No	O	NA	R (08AUG2020)	N/N
			Lumbar vertebral fracture/ L2/L3 Fracture	1	08AUG2020	8/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1128 11281018	3^	GASTR	Abdominal pain upper/ STOMACH PAIN	2	03SEP2020	15/22	2	No	O	NA/TC	R (24SEP2020)	N/N
		GENRL	Chest discomfort/ CENTRAL CHEST DISCOMFORT	2	10OCT2020	52/1	2	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1128 11281057	3^	INFEC	Tonsillitis/ tonsillitis	2	19SEP2020	25/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1128 11281061	3^	INJ&P	Muscle strain/ intercostal muscle strain	1	07AUG2020	1/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1128 11281064	3^	EAR	Vertigo/ Vertigo	2	31AUG2020	5/4	1	No	O	NA/TCN	R (03SEP2020)	N/N
		METAB	Dehydration/ dehydration	2	08OCT2020	43/3	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1128 11281078	3^	INFEC	Kidney infection/ Kidney Infection	1	15AUG2020	9/7	2	No	O	NA/TC	R (21AUG2020)	N/N
		UNC	URINARY TRACT INFECTION@@/ URINARY TRACT INFECTION	1	15AUG2020	9/7	2	No	O	NA/TC	R (21AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Nasal congestion/ Nasal Congestion	2	02OCT2020	38/6	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C459100 11128 11281098	3^	SKIN	Macule/ Erythematous, Macule upper anterior thigh	2	13SEP2020	10/27	2	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C459100 11128 11281101	3^	MUSC	Arthralgia/ Bilateral Knee Pain	1	15AUG2020	4/C	1	No	O	NA/TC/TCN	N	N/N
16-55/ C459100 11128 11281103	3^	INFEC	Escherichia urinary tract infection/ Escherichia coli urinary tract infection	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N
		INV	Blood potassium decreased/ Low potassium	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N
		RENAL	Nephrolithiasis/ Kidney Stones	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N
16-55/ C459100 11128 11281107	3^	NERV	Presyncope/ presyncope (following blood draw)*		12AUG2020	1/1	2	Yes		NA	R (12AUG2020)	N/N
16-55/ C459100 11128 11281119	3^	GASTR	Nausea/ nausea	1	27AUG2020	14/1	2	No	O	NA	R (27AUG2020)	N/N
			Vomiting/ vomiting	1	27AUG2020	14/4	2	No	O	NA	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11128 11281128	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	1	06SEP2020	21/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 11128 11281129	3^	GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 11128 11281143	3^	INJ&P	Muscle strain/ Bilateral LEG muscle strain	2	18SEP2020	9/C	2	No	O	NA/TC	N	N/N
		MUSC	Spondylitis/ unknown LUMBAR INFLAMATION	2	18SEP2020	9/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 11128 11281147	3^	GENRL	Pain/ Body aches	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ Fever	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 11128 11281157	3^	GENRL	Pain/ Body aches	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
			Pyrexia/ Fever	1	21AUG2020	2/2	2	Yes		NA/TC	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11128 11281170	3^	NERV	Headache/ Headache	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Pain/ Body aches	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ Fever	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ Headache	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Pain/ Body Aches	1	25AUG2020	2/3	1	Yes		NA/TC	R (27AUG2020)	N/N
		RESP	Paranasal sinus discomfort/ Nasal Sinus Discomfort	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
		INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	2	12OCT2020	28/7	1	No	O	NA	R (18OCT2020)	N/N
		MUSC	Arthritis/ RIGHT SHOULDER INFLAMATION	1	17SEP2020	25/1	1	No	O	NA/TC	R (17SEP2020)	N/N
		16-55/ C459100 11128 11281175	3^	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA
			Pain/ Body Aches	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
			Pyrexia/ Subjective Fever	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11128 11281176	3^	NERV	Syncope/ vasovagal syncope*		24AUG2020	1/1	3	No	O	NA	R (24AUG2020)	N/N
		GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
			Pain/ Body Aches	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
			Pyrexia/ Subject Fever	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C459100 11128 11281190	3^	GENRL	Pain/ Body Aches	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ Subjective Fever	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ Headaches	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 11128 11281195	3^	GASTR	Toothache/ Toothache, upper right side	1	27AUG2020	3/1	1	No	O	NA	R (27AUG2020)	N/N
		GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
			Pain/ generalized body aches	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
			Pyrexia/ Fever	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11128 11281198	3^	BLOOD	Lymphadenopathy/ Axillary Adenopathy, left side	1	26AUG2020	1/4	1	Yes		NA/TCN	R (29AUG2020)	N/N
16-55/ C459100 11128 11281199	3^	RENAL	Haematuria/ hematuria	2	15OCT2020	29/1	1	No	O	NA	R (15OCT2020)	N/N
16-55/ C459100 11128 11281220	3^	GASTR	Nausea/ NAUSEA	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Pyrexia/ FEVER (101)	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 11128 11281225	3^	GENRL	Injection site pain/ Soreness at injection site, left arm	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
			Pain/ Body Aches	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 11128 11281228	3^	GENRL	Chills/ CHILLS	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN, RIGHT ARM	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1128 11281231	3^	NERV	Headache/ HEADACHE	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ Soreness left arm, at injection site.*		31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Injection site pain/ Soreness left arm, at injection site.	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Pyrexia/ Subjective fever	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C459100 1 1128 11281232	3^	NERV	Headache/ Headache	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C459100 1 1128 11281235	3^	GENRL	Fatigue/ FATIGUE	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		INFEC	Bacterial vulvovaginitis/ Bacterial Vaginitis	2	15OCT2020	25/5	1	No	O	NA/TC	R (19OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11128 11281247	3^	NERV	Dizziness/ Dizziness*		01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Pyrexia/ SUBJECTIVE FEVER	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		GASTR	Nausea/ NAUSEA	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		RESP	Cough/ COUGH	2	24SEP2020	2/2	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C459100 11128 11281257	3^	GENRL	Nasal congestion/ NASAL CONGESTION	2	24SEP2020	2/2	1	No	O	NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN, LEFT ARM	1	01SEP2020	1/5	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Fatigue/ FATIGUE	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	2	22SEP2020	2/2	1	Yes		NA/TCN	R (23SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11128 11281268	3^	MUSC	Myalgia/ SORE NECK MUSCLES	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ SORENESS AT INJECTION SITE, LEFT ARM	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
16-55/ C459100 11128 11281269	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE, LEFT ARM	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	1	04SEP2020	3/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 11128 11281274	3^	NERV	Headache/ HEADACHE	1	05SEP2020	4/1	1	Yes		NA/TC	R (05SEP2020)	N/N
		GENRL	Injection site pain/ SORENESS AT INJECTION SITE, LEFT	1	07SEP2020	6/2	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C459100 11128 11281286	3^	GENRL	Chills/ Chills	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N
		INFEC	Vulvovaginal mycotic infection/ Vaginal Yeast Infection	1	04SEP2020	1/6	2	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C459100 11128 11281288	3^	INFEC	Ear infection/ Ear Infection	2	30SEP2020	6/10	2	No	O	NA	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1128 11281289	3^	RESP	Respiratory tract congestion/ Chest Congestion	2	30SEP2020	6/10	1	No	O	NA/TC	R (09OCT2020)	N/N
		GENRL	Chills/ Chills	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
			Injection site pain/ left arm injection site pain/soreness	1	04SEP2020	1/5	1	Yes		NA	R (08SEP2020)	N/N
			Pyrexia/ Subjective Fever	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
			Pain/ BODY ACHES	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1128 11281294	3^	GENRL	Pyrexia/ SUBJECTIVE FEVER	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Chills/ Chills	2	04OCT2020	2/2	1	Yes		NA/TC	R (05OCT2020)	N/N
			Pain/ body aches	2	04OCT2020	2/2	1	Yes		NA/TC	R (05OCT2020)	N/N
			Pyrexia/ Subjective fever (99.7)	2	04OCT2020	2/2	1	Yes		NA/TC	R (05OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11128 11281301	3^	GENRL	Chills/ Chills	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Fatigue	2	29SEP2020	2/4	2	Yes		NA	R (02OCT2020)	N/N
			Pyrexia/ Subjective Fever	2	29SEP2020	2/1	1	Yes		NA/TC	R (29SEP2020)	N/N
		SKIN	Night sweats/ Night Sweats	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 11128 11281306	3^	GENRL	Chills/ CHILLS	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
			Fatigue/ FATIGUE	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
			Pain/ BODY ACHE	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 11128 11281309	3^	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	01OCT2020	3/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 11128 11281311	3^	GENRL	Pyrexia/ Subjective Fever	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ chills	2	04OCT2020	2/1	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1128 11281332												
16-55/ C459100	3^	GENRL	Chills/ Chills	1	03OCT2020	23/1	1	Yes		NA	R (03OCT2020)	N/N
1 1128 11281334												
			Pain/ Body Aches	1	03OCT2020	23/1	1	Yes		NA	R (03OCT2020)	N/N
			Pyrexia/ Fever	1	03OCT2020	23/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100	3^	GENRL	Pain/ Aches/Pain	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
1 1128 11281345												
			Pyrexia/ Subjective Fever	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100	3^	BLOOD	Lymphadenopathy/ Left Supraclavicular Adenopathy	2	07OCT2020	2/C	2	Yes		NA/TC	RG	N/N
1 1128 11281359												
		GENRL	Injection site pain/ Left Arm injection site Pain	2	07OCT2020	2/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100	3^	GENRL	Chills/ CHILLS	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
1 1128 11281384												
16-55/ C459100	3^	GENRL	Injection site pain/ Soreness left arm, at injection site.	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11128 11281385		GENRL	Fatigue/ Fatigue	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
			Pyrexia/ subjective fever	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 11129 11291029	3^	INFEC	Vulval abscess/ worsening furuncle vulva	2	30SEP2020	38/31	2	No	O	NA/TC	R (30OCT2020)	N/N
16-55/ C459100 11129 11291042	3^	GASTR	Dyspepsia/ Dyspepsia	1	08AUG2020	5/4	2	No	O	NA/TC	R (11AUG2020)	N/N
16-55/ C459100 11129 11291061	3^	INJ&P	Foot fracture/ fracture right great toe	2	10OCT2020	47/C	2	No	O	NA/TCN	RG	N/N
			Foot fracture/ fracture right second toe	2	10OCT2020	47/C	2	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 11129 11291072	3^	MUSC	Back pain/ low back pain	2	31AUG2020	1/26	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C459100	3^	NEOPL	Benign breast neoplasm/ benign breast nodules bilateral	1	17AUG2020	7/10	2	No	O	NA/TC/TCN	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1129 11291092 16-55/ C459100	3^	NERV	Headache/ Headache	2	09OCT2020	26/3	1	No	O	NA/TC	R (11OCT2020)	N/N
1 1129 11291142		RESP	Sinus congestion/ sinus congestion	2	09OCT2020	26/3	1	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C459100 1 1129 11291148	3^	INJ&P	Muscle strain/ neck muscle strain	1	11SEP2020	18/4	1	No	O	NA/TC	R (14SEP2020)	N/N
16-55/ C459100 1 1129 11291153	3^	MUSC	Myalgia/ myalgias	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1129 11291157	3^	MUSC	Myalgia/ Left deltoid tenderness	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 1 1129 11291165	3^	GENRL	Chest pain/ Acute chest pain	1	13SEP2020	6/19	2	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1129 11291187	3^	GENRL	Pyrexia/ fever	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11129 11291197	3^	MUSC	Myalgia/ muscle aches	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
		NERV	Headache/ headache	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
		GASTR	Nausea/ Nausea	1	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Injection site pain/ Left arm injection site soreness	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		GASTR	Lip swelling/ Upper lip swelling	1	06OCT2020	15/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 11129 11291201	3^	GASTR	Lip swelling/ lower lip swelling	1	11OCT2020	20/2	1	Yes		NA/TC	R (12OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
		MUSC	Myalgia/ Left Deltoid tenderness	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ left deltoid tenderness	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 11129 11291202	3^	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	1	26SEP2020	5/5	1	No	O	NA	R (30SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ fatigue	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11129 11291210		MUSC	Myalgia/ left deltoid tenderness	1	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 11129 11291212	3^	MUSC	Myalgia/ right deltoid muscle tenderness	1	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11130 11301001	3^	GENRL	Chills/ chills	2	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		MUSC	Myalgia/ muscle aches in bilateral legs	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 11130 11301002	3^	REPRO	Breast pain/ bilateral breast pain	1	25AUG2020	2/28	1	No	O	NA	R (21SEP2020)	N/N
16-55/ C459100 11130 11301032	3^	GASTR	Vomiting/ emesis	1	02SEP2020	1/1	1	No	O	NA	R (02SEP2020)	N/N
		NERV	Presyncope/ near syncope*		02SEP2020	1/1	1	No	O	NA	R (02SEP2020)	N/N
16-55/ C459100	3^	RESP	Cough/ Cough	1	19SEP2020	18/4	1	No	O	NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1130 11301033	3^	NERV	Headache/ Headache	2	28SEP2020	1/8	1	Yes		NA	R (05OCT2020)	N/N
1 1130 11301056	3^	EAR	Vertigo positional/ Benign paroxysmal positional vertigo	1	19SEP2020	10/6	1	No	O	NA/TC/TCN	R (24SEP2020)	N/N
1 1130 11301064	3^	INJ&P	Eye contusion/ contusion of right eye	2	25SEP2020	18/5	1	No	O	NA	R (29SEP2020)	N/N
1 1131 11311015	3^	MUSC	Coccydynia/ coccygeal pain	2	21OCT2020	50/C	2	No	O	NA/TCN	N	N/N
1 1131 11311024	3^	IMMUN	Drug hypersensitivity/ allergic reaction, potentially related to study drug	1	17AUG2020	1/1	2	Yes		NA/TC	R (17AUG2020)	N/N
		SKIN	Urticaria/ allergic reaction, one hive appearing on right armpit	1	17AUG2020	1/1	2	Yes		NA/TC	R (17AUG2020)	N/N
		NERV	Headache/ headache	1	18AUG2020	2/4	2	Yes		NA/TC	R (21AUG2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ fatigue	2	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1131 11311035		MUSC	Myalgia/ muscle aches	2	09SEP2020	2/2	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1131 11311042	3^	INJ&P	Ligament sprain/ sprained left ankle	2	03OCT2020	26/39	2	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C459100 1 1131 11311046	3^	GENRL	Fatigue/ fatigue	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
			Pyrexia/ fever	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		SURG	Endodontic procedure/ root canal	2	28SEP2020	18/1	2	No	O	NA/TCN	R (28SEP2020)	N/N
16-55/ C459100 1 1131 11311053	3^	GENRL	Chills/ chills	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/Y
			Pain/ body aches	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/Y
		INV	Body temperature increased/ elevated temperature	2	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/Y
16-55/ C459100 1 1131 11311069	3^	NERV	Dizziness/ light headedness	2	11SEP2020	2/5	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11131 11311071	3^	INJ&P	Procedural pain/ left arm pain post injection	1	22AUG2020	2/2	2	Yes		NA	R (23AUG2020)	N/N
		GENRL	Injection site pain/ left arm injection site pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		SKIN	Rash/ rash across chest	2	09SEP2020	1/6	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C459100 11131 11311073	3^	MUSC	Back pain/ left side low back pain	2	27SEP2020	14/10	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100 11131 11311076	3^	MUSC	Arthralgia/ generalized joint pain	1	26AUG2020	3/16	1	No	O	NA	R (10SEP2020)	N/N
16-55/ C459100 11131 11311080	3^	GENRL	Chills/ chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Fatigue/ fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 11131 11311081	3^	NERV	Presyncope/ Near syncope*		25AUG2020	1/1	1	No	O	NA	R (25AUG2020)	N/N
16-55/ C459100 11131 11311090	3^	GENRL	Injection site haematoma/ injection site hematoma	2	18SEP2020	1/6	1	No	O	NA	RS (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11131 11311097	3^	SKIN	Pruritus/ generalized pruritus	1	28AUG2020	2/1	1	Yes		NA/TC	R (28AUG2020)	N/N
16-55/ C459100 11131 11311104	3^	GENRL	Chills/ chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Fatigue/ fatigue	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 11131 11311107	3^	GENRL	Injection site pain/ injection site tenderness	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C459100 11131 11311117	3^	UNC	WORSENING OF DIZZINESS@@/ Worsening of dizziness	2	08NOV2020	48/2	3	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C459100 11131 11311124	3^	GENRL	Injection site pain/ Injection site arm pain	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C459100 11131 11311129	3^	GENRL	Injection site pain/ Injection site pain in arm	2	24SEP2020	1/4	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 11131 11311132	3^	INJ&P	Contusion/ right sided facial bruising	2	11OCT2020	20/8	1	No	O	NA	RS (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11131 11311134	3^	MUSC	Contusion/ right-sided shoulder bruising	2	11OCT2020	20/8	2	No	O	NA	R (18OCT2020)	N/N
			Fall/ mechanical fall	2	11OCT2020	20/1	2	No	O	NA	R (11OCT2020)	N/N
			Arthralgia/ shoulder pain, right	2	11OCT2020	20/C	2	No	O	NA/TC	N	N/N
			Contusion/ contusion on right thigh	1	17SEP2020	15/15	2	No	O	NA	R (01OCT2020)	N/N
			Road traffic accident/ bicycle accident	1	17SEP2020	15/1	2	No	O	NA	R (17SEP2020)	N/N
16-55/ C459100 11131 11311136	3^	GENRL	Skin abrasion/ abrasion right forearm	1	17SEP2020	15/15	2	No	O	NA/TCN	R (01OCT2020)	N/N
			Injection site pain/ injection site arm pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
			Decreased appetite/ decreased appetite	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Night sweats/ night sweats	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 11131 11311147	3^	GENRL	Injection site pain/ injection site pain in left arm	2	29SEP2020	2/3	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100	3^	GASTR	Nausea/ nausea	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1131 11311148		GENRL	Chills/ chills	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
			Injection site pain/ arm pain at injection site	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
			Pyrexia/ fever	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		MUSC	Myalgia/ muscle pain	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1131 11311152	3^	INJ&P	Fall/ Fall	1	25SEP2020	17/1	1	No	O	NA	RS (25SEP2020)	N/N
			Skin abrasion/ bilateral knee abrasion	1	25SEP2020	17/21	1	No	O	NA/TC/TCN	RS (15OCT2020)	N/N
		INFEC	Carbuncle/ both axillary carbuncles	2	24OCT2020	25/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1131 11311162	3^	MUSC	Myalgia/ muscle pain in back	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1131 11311172	3^	MUSC	Joint swelling/ right knee swelling	2	02NOV2020	32/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ injection site pain	2	02OCT2020	2/7	1	Yes		NA/TC	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1131 11311173 16-55/ C459100 1 1131 11311178	3^	GENRL	Pyrexia/ fever, 100.7 degrees Fahrenheit	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
		MUSC	Myalgia/ muscle aches	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1131 11311181	3^	GENRL	Chills/ Chills	2	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1131 11311183	3^	NERV	Syncope/ vasovagal episode with syncope*		16SEP2020	1/1	1	No	O	NA	R (16SEP2020)	N/N
16-55/ C459100 1 1131 11311190	3^	RESP	Sinus congestion/ Sinus congestion	1	06OCT2020	19/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1131 11311193	3^	GENRL	Pain/ generalized body pain	1	04OCT2020	17/C	2	No	O	NA/TC	RG	N/N
		INJ&P	Rib fracture/ fracture of left rib	1	04OCT2020	17/C	2	No	O	NA/TC	RG	N/N
			Road traffic accident/ bicycle collision with motor vehicle	1	04OCT2020	17/1	2	No	O	NA/TC	RS (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Skin laceration/ laceration of left elbow	1	04OCT2020	17/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 11131 11311201	3^	GENRL	Fatigue/ fatigue	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Chills/ chills	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
			Fatigue/ fatigue	2	12OCT2020	1/C	1	Yes		NA	RG	N/N
		INV	Body temperature increased/ elevated temperature, low grade	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ generalized myalgia	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 11131 11311228	3^	NERV	Migraine/ migraine	1	01OCT2020	2/4	2	No	O	NA/TC	R (04OCT2020)	N/N
		VASC	Hypertension/ worsening hypertension	1	01OCT2020	2/3	1	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C459100 11131 11311232	3^	GENRL	Injection site pain/ injection site pain	1	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 11133 11331059	3^	GASTR	Vomiting/ vomiting	2	10OCT2020	25/2	2	No	O	NA/TC	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11133 11331113	3^	NERV	Headache/ headache	2	27OCT2020	60/5	2	No	O	NA/TC	R (31OCT2020)	N/N
16-55/ C459100 11133 11331115	3^	GASTR	Vomiting/ vomiting	2	19SEP2020	22/2	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C459100 11133 11331117	3^	INJ&P	Thermal burn/ right calf skin burn due to contact with very hot motorcycle pipe exhaust.	1	15AUG2020	8/45	2	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C459100 11133 11331119	3^	NERV	Headache/ headache	1	04SEP2020	24/1	1	No	O	NA	R (04SEP2020)	N/N
		RESP	Nasal congestion/ NASAL CONGESTION	1	04SEP2020	24/6	1	No	O	NA	R (09SEP2020)	N/N
16-55/ C459100 11133 11331120	3^	UNC	UPPER RESPIRATORY INFECCION@@/ Upper Respiratory Infeccion	2	01NOV2020	33/C	2	No		NA	N	N/N
16-55/ C459100 11133 11331139	3^	MUSC	Arthralgia/ Worsening left Hip Pain	2	06SEP2020	3/C	1	No	O	NA	RG	N/N
			Arthralgia/ Worsening left elbow pain	2	06SEP2020	3/C	1	No	O	NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11133 11331152	3^	SKIN	Rash/ Intermittent Rash (arms, legs, and abdomen)	1	31AUG2020	18/9	2	Yes		NA/TC	R (08SEP2020)	N/N
16-55/ C459100 11133 11331170	3^	VASC	Hypertension/ Worsening of Hypertension	1	04SEP2020	22/C	2	No	O	P/TC	N	N/N
16-55/ C459100 11133 11331188	3^	GENRL	Pain/ Body Ache	1	31AUG2020	13/4	2	Yes		NA/TC	R (03SEP2020)	N/N
		NERV	Headache/ Headache	1	31AUG2020	13/4	2	Yes		NA/TC	R (03SEP2020)	N/N
16-55/ C459100 11133 11331195	3^	MUSC	Arthralgia/ JOINT PAIN BOTH ARMS	2	12SEP2020	4/C	1	Yes		NA	N	N/N
16-55/ C459100 11133 11331198	3^	GENRL	Chills/ CHILLS	2	16SEP2020	8/2	1	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ FEVER	2	16SEP2020	8/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11133 11331207	3^	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	1	20AUG2020	2/38		No	O	NA/TC	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11133 11331230	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ injection site pain	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 11133 11331263	3^	GENRL	Malaise/ malaise	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
		RESP	Cough/ cough	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Fatigue/ tiredness	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ injection site pain	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
		MUSC	Musculoskeletal discomfort/ back discomfort	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ headaches	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 11133 11331265	3^	GENRL	Chills/ CHILLS	2	20SEP2020	5/1	1	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	20SEP2020	5/1	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100	3^	MUSC	Back pain/ back pain	2	19SEP2020	2/3	2	No	CND	NA/TC	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1133 11331266	3^	GASTR	Diarrhoea/ Diarrhea	1	04SEP2020	9/2	1	Yes		NA	R (05SEP2020)	N/N
1 1133 11331278	3^	GENRL	Injection site pain/ injection site soreness	1	27AUG2020	1/5	1	Yes		NA	R (31AUG2020)	N/N
1 1133 11331282		GENRL	Pyrexia/ fever	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
		NERV	Headache/ headaches	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100 1 1133 11331292	3^	GASTR	Diarrhoea/ DIARRHEA	1	17SEP2020	22/1	1	No	O	NA	R (17SEP2020)	N/N
16-55/ C459100 1 1133 11331293	3^	RESP	Oropharyngeal pain/ Sore Throat	1	12SEP2020	17/2	1	No	O	NA	R (13SEP2020)	N/N
16-55/ C459100 1 1133 11331313	3^	GENRL	Chills/ CHILLS	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ FEVER	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1133 11331328	3^	NERV	Headache/ HEADACHE	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
		GENRL	Injection site pain/ Soreness injection site	1	30AUG2020	2/2	1	Yes		NA	R (31AUG2020)	N/N	
		EAR	Tinnitus/ Tinnitus	1	14SEP2020	17/C	2	No	O	NA	N	N/N	
		NERV	Headache/ Headache	1	14SEP2020	17/C	1	Yes		NA/TCN	N	N/N	
		3^	INFEC	Upper respiratory tract infection/ UPPER Respiratory Infection	1	20SEP2020	23/4	2	No	O	NA/TC	R (23SEP2020)	N/N
		3^	GENRL	Chills/ CHILLS	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
			MUSC	Myalgia/ MUSCLE ACHES	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
		3^	GASTR	Diarrhoea/ DIARRHEA	2	23SEP2020	1/4	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	23SEP2020	1/4	2	Yes		NA/TC/TCN	R (26SEP2020)	N/N	
			Pyrexia/ FEVER	2	23SEP2020	1/4	2	Yes		NA/TC/TCN	R (26SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1133 11331367	3^	NERV	Headache/ HEADACHE	2	23SEP2020	1/4	2	Yes		NA/TC	R (26SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ FEVER	2	23SEP2020	1/2	2	Yes		NA/TC/TCN	R (24SEP2020)	N/N
16-55/ C459100 1 1133 11331370	3^	GASTR	Vomiting/ VOMITING (ONE EPISODE)	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Pyrexia/ FEVER	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1133 11331376	3^	GENRL	Pyrexia/ FEVER	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C459100 1 1133 11331385	3^	INV	Blood glucose abnormal/ UNCONTROLLED BLOOD SUGAR LEVEL	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
		MUSC	Arthralgia/ JOINT PAIN	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
		GENRL	Pyrexia/ FEVER	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100	3^	EAR	Vertigo/ Vertigo	2	30SEP2020	8/11	2	No	O	NA/TC	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1133 11331387		GASTR	Abdominal discomfort/ Stomach upset	2	30SEP2020	8/11	2	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1133 11331388	3^	GENRL	Injection site pain/ PAIN IN INJECTION SITE	2	26SEP2020	2/5	1	Yes		NA/TC	R (30SEP2020)	N/N
			Pain/ BODY ACHES	2	26SEP2020	2/15	1	Yes		NA/TC	R (10OCT2020)	N/N
		MUSC	Musculoskeletal discomfort/ NECK DISCOMFORT	2	26SEP2020	2/5	1	Yes		NA/TC	R (30SEP2020)	N/N
		NERV	Tension headache/ tension HEADACHE	2	26SEP2020	2/3	1	Yes		NA/TC	R (28SEP2020)	N/N
16-55/ C459100 1 1133 11331398	3^	GENRL	Pyrexia/ FEVER	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1133 11331419	3^	INJ&P	Thermal burn/ left wrist burn	1	17SEP2020	9/5	1	No	O	NA	R (21SEP2020)	N/N
16-55/ C459100 1 1133 11331441	3^	INFEC	Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION (URI)	2	02OCT2020	3/21	1	No	O	NA	R (22OCT2020)	N/N
16-55/ C459100	3^	METAB	Diabetes mellitus/ WORSENING OF DIABETES	2	11OCT2020	3/1	2	No	O	NA/TC	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1133 11331450	3^	GENRL	Chills/ chills	1	19SEP2020	2/2	2	Yes		NA/TC/TCN	R (20SEP2020)	N/N
1 1133 11331460			Injection site pain/ injection site pain	1	19SEP2020	2/2	2	Yes		NA/TC/TCN	R (20SEP2020)	N/N
		MUSC	Arthralgia/ joint pain	1	19SEP2020	2/2	2	Yes		NA/TC/TCN	R (20SEP2020)	N/N
16-55/ C459100 1 1133 11331463	3^	GENRL	Pain/ body aches	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ fever	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1133 11331465	3^	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	2	15OCT2020	7/6	1	No	O	NA/TCN	R (20OCT2020)	N/N
16-55/ C459100 1 1133 11331474	3^	RESP	Rhinorrhoea/ RUNNY NOSE	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA (1 EPISODE)	1	21SEP2020	4/1	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100	3^	GASTR	Vomiting/ EMESIS	1	03OCT2020	11/2	2	No	O	NA/TC	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1133 11331495		GENRL	Pyrexia/ FEVER	2	15OCT2020	2/6	2	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C459100 1 1133 11331496	3 [†]	INJ&P	Foot fracture/ BROKEN PINKY ON LEFT FOOT	1	29SEP2020	7/C	2	No	O	NA/TCN	N	N/N
16-55/ C459100 1 1133 11331505	3 [^]	GENRL	Influenza like illness/ FLU-LIKE SYMPTOMS	2	14OCT2020	1/13	2	Yes		NA/TC/TCN	R (26OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	14OCT2020	1/7	2	Yes		NA/TC/TCN	R (20OCT2020)	N/N
16-55/ C459100 1 1133 11331506	3 [^]	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	14OCT2020	1/5	2	Yes		NA/TC/TCN	R (18OCT2020)	N/N
		GENRL	Influenza like illness/ FLU-LIKE SYMPTOMS	2	15OCT2020	2/2	2	Yes		NA/TC/TCN	R (16OCT2020)	N/N
16-55/ C459100 1 1134 11341005	3 [^]	MUSC	Joint effusion/ Left Knee Pain secondary to joint effusion	1	14AUG2020	9/15	2	No	O	NA/TC	R (28AUG2020)	N/N
16-55/ C459100 1 1134 11341070	3 [^]	GASTR	Diarrhoea/ Diarrhea	1	18AUG2020	6/2	1	Yes		NA	R (19AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11134 11341153	3^	EYE	Eye pain/ right eye pain	1	25AUG2020	2/28	2	Yes		P	R (21SEP2020)	N/N
		GASTR	Abdominal discomfort/ upset stomach	1	25AUG2020	2/28	2	Yes		P/TC	R (21SEP2020)	N/N
			Diarrhoea/ diarrhea	1	25AUG2020	2/1	1	Yes		P	R (25AUG2020)	N/N
			Diarrhoea/ loose stools	1	25AUG2020	2/28	2	Yes		P	R (21SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	25AUG2020	2/28	2	Yes		P	R (21SEP2020)	N/N
		MUSC	Muscular weakness/ muscle weakness	1	25AUG2020	2/28	2	Yes		P	R (21SEP2020)	N/N
		NERV	Headache/ headache	1	25AUG2020	2/1	1	Yes		P	R (25AUG2020)	N/N
16-55/ C459100 11134 11341174	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	26AUG2020	1/5	3	Yes		P	R (30AUG2020)	N/N
		NERV	Headache/ WORSENING HEADACHE	1	27AUG2020	2/8	2	Yes		P/TC	R (03SEP2020)	N/N
		MUSC	Pain in extremity/ ARM PAIN (LEFT)	1	28AUG2020	3/6	3	Yes		P/TC	R (02SEP2020)	N/N
		GENRL	Chest discomfort/ CHEST TIGHTNESS	1	30AUG2020	5/8	2	Yes		NA/TC	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		METAB	Hypokalaemia/ HYPOKALEMIA	1	30AUG2020	5/3	1	No	O	NA/TC	R (01SEP2020)	N/N
16-55/ C459100 1 1134 11341225	3^	GENRL	Injection site pain/ Left Arm Soreness at the injection site	1	31AUG2020	1/4	2	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 1 1134 11341228	3^	MUSC	Intervertebral disc protrusion/ Worsening Herniated Lumbar Disc	1	12SEP2020	12/7	2	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1134 11341308	3^	GASTR	Nausea/ NAUSEA	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Injection site pain/ PAIN AT INJECTION SITE	1	09SEP2020	1/3	2	Yes		NA/TC	R (11SEP2020)	N/N
			Injection site swelling/ SWELLING AT INJECTION SITE	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1134 11341321	3^	GENRL	Injection site pain/ Pain at injection site*		10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1134 11341325	3^	GENRL	Injection site pain/ Shoulder Pain on Injection arm	2	02OCT2020	1/4	2	Yes		NA	R (05OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1134 11341378	3^	SKIN	Hyperhidrosis/ Sweating	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	03OCT2020	2/3	1	Yes		NA	RG (05OCT2020)	N/N
		GASTR	Nausea/ NAUSEA	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
			Pain/ BODY ACHES	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C459100 1 1134 11341381	3^	NERV	Facial paralysis/ Bell's Palsy	2	04NOV2020	9/C	2	Yes		NA/TC	RG	N/N
		GENRL	Injection site erythema/ Injection Site Redness	2	26OCT2020	1/7	2	Yes		NA	R (01NOV2020)	N/N
16-55/ C459100 1 1134 11341393	3^		Injection site swelling/ Injection Site Swelling	2	26OCT2020	1/7	2	Yes		NA	R (01NOV2020)	N/N
		NERV	Presyncope/ vasovagal reaction*		09OCT2020	1/1	2	No	O	NA	R (09OCT2020)	N/N
16-55/ C459100	3^	GENRL	Pyrexia/ fever	2	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1135 11351025		NERV	Headache/ headache	2	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N
16-55/ C459100 1 1135 11351037	3^	INFEC	Urinary tract infection/ urinary tract infection	1	07AUG2020	3/11	1	No	O	NA/TC	R (17AUG2020)	N/N
16-55/ C459100 1 1135 11351041	3^	GASTR	Dyspepsia/ exacerbation of heartburn	2	04SEP2020	8/5	1	No	O	NA/TC	R (08SEP2020)	N/N
16-55/ C459100 1 1135 11351052	3^	SKIN	Skin ulcer/ foot ulcer	2	28AUG2020	2/11	1	No	O	NA	R (07SEP2020)	N/N
16-55/ C459100 1 1135 11351057	3^	INFEC	Hordeolum/ left eye stye	1	15AUG2020	9/46	1	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C459100 1 1135 11351061	3^	SKIN	Dermatitis contact/ allergic reaction to poison oak (left arm)	1	18AUG2020	12/16	2	No	O	NA/TC	R (02SEP2020)	N/N
16-55/ C459100 1 1135 11351105	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	13AUG2020	2/13	1	No	O	NA/TC	R (25AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Back pain/ lower back pain	1	13AUG2020	2/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1135 11351121	3^	INFEC	Herpes zoster/ shingles	1	17AUG2020	5/8	1	No	O	NA/TC	R (24AUG2020)	N/N
16-55/ C459100 1 1135 11351142	3^	GASTR	Nausea/ Nausea	1	17AUG2020	1/3	1	No	O	NA	R (19AUG2020)	N/N
		GASTR	Dental caries/ dental caries	1	04SEP2020	19/1	1	No	O	NA/TC	R (04SEP2020)	N/N
16-55/ C459100 1 1135 11351144	3^	MUSC	Back pain/ lower back pain	1	10SEP2020	25/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1135 11351151	3^	MUSC	Pain in extremity/ Left arm pain	1	22AUG2020	5/2	1	No	O	NA	R (23AUG2020)	N/N
16-55/ C459100 1 1135 11351158	3^	MUSC	Pain in extremity/ soreness on both arms and legs	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1135 11351163	3^	GENRL	Fatigue/ fatigue	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
		NERV	Headache/ headache	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11135 11351166	3^	GENRL	Chills/ chills	2	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
			Pain/ bodyaches	2	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		NERV	Headache/ headache	1	10SEP2020	22/2	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 11135 11351168	3^	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 11135 11351172	3^	GASTR	Diarrhoea/ loose stool	2	12OCT2020	33/C	1	No	O	NA	RG	N/N
16-55/ C459100 11135 11351178	3^	INFEC	Cellulitis/ left toe cellulitis	2	25SEP2020	16/4	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C459100 11135 11351179	3^	NERV	Syncope/ syncope episode*		21AUG2020	1/1	1	No	O	NA	R (21AUG2020)	N/N
16-55/ C459100 11135 11351190	3^	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ Fever	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1135 11351198	3^	NERV	Headache/ headache	1	24AUG2020	1/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1135 11351201	3^	GENRL	Pain/ body aches	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	18SEP2020	2/3	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100 1 1135 11351205	3^	GASTR	Diarrhoea/ loose bowel movement	1	07SEP2020	14/1	1	No	O	NA/TC	R (07SEP2020)	N/N
16-55/ C459100 1 1135 11351222	3^	GENRL	Injection site pain/ soreness left upper arm injection site	1	31AUG2020	1/2	1	Yes		NA/TC	R (01SEP2020)	N/N
16-55/ C459100 1 1135 11351227	3^	GENRL	Injection site pain/ Pain at Injection Site	1	01SEP2020	2/4	1	Yes		NA	R (04SEP2020)	N/N
			Pain/ Body Aches	1	01SEP2020	2/4	1	Yes		NA	R (04SEP2020)	N/N
		RESP	Nasal congestion/ Nasal Congestion	1	01SEP2020	2/4	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ chills	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
			Injection site pain/ pain at injection site	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
			Pain/ body aches	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1135 11351228	3^	GENRL	Fatigue/ fatigue	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Injection site pain/ Pain on Injection Site	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
			Pain/ Body Aches	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
			Pyrexia/ Fever	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C459100 1 1135 11351235	3^	NERV	Syncope/ vasovagal syncope*		31AUG2020	1/1	1	No	O	NA	R (31AUG2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1135 11351243			Pain/ Body Aches	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1135 11351251	3^	GENRL	Pain/ body aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Pain/ Body Aches	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1135 11351256	3^	MUSC	Myalgia/ Muscle Aches	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1135 11351265	3^	MUSC	Arthralgia/ pain on right knee	2	30OCT2020	36/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1135 11351269	3^	GENRL	Pain/ body aches	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		NERV	Lethargy/ lethargy	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1135 11351276			Pain/ Body Aches	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1135 11351290	3^	GENRL	Injection site pain/ Injection site soreness	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1135 11351292	3^	GENRL	Chills/ chills	1	04SEP2020	2/32	1	Yes		NA	R (05OCT2020)	N/N
			Pain/ body aches	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
			Pyrexia/ fever	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100	3^	GENRL	Pain/ body aches	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1135 11351297			Pyrexia/ low grade temperature	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C459100 1 1135 11351323	3^	GASTR	Diarrhoea/ loose bowel movement	1	13SEP2020	6/1	1	No	O	NA	R (13SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 1 1135 11351326	3^	GASTR	Diarrhoea/ loose stool	2	02OCT2020	4/C	1	No	O	NA/TCN	RG	N/N
			Gastrointestinal sounds abnormal/ borborygmus	2	02OCT2020	4/C	1	No	O	NA/TCN	RG	N/N
16-55/ C459100 1 1135 11351330	3^	GENRL	Injection site pain/ pain at injection site	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1135 11351332	3^	INFEC	Urinary tract infection/ urinary tract infection	1	14SEP2020	6/8	1	No	O	NA/TC	R (21SEP2020)	N/N
16-55/ C459100 1 1135 11351349	3^	GENRL	Chills/ Chills	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ headache	2	02OCT2020	1/3	2	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 1135 11351359	3^	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	1	01OCT2020	15/6	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1135 11351373	3^	GASTR	Diarrhoea/ diarrhea	1	24SEP2020	7/2	1	No	O	NA/TC/TCN	R (25SEP2020)	N/N
16-55/ C459100 1 1135 11351376	3^	PSYCH	Anxiety/ worsening of anxiety	2	01NOV2020	23/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1135 11351377	3^	GENRL	Chills/ Chills	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
			Fatigue/ fatigue	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
			Pain/ Body Aches	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
		NERV	Headache/ Headache	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1135 11351381	3^	GENRL	Pyrexia/ fever (subjective) - low grade	2	01NOV2020	24/2	1	No	O	NA/TC	R (02NOV2020)	N/N
1 1135 11351391		GASTR	Toothache/ pain - right molar bottom tooth	2	03NOV2020	26/1	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C459100 1 1135 11351391	3^	GENRL	Injection site pain/ soreness at injection site - left arm	1	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1135 11351403	3^	MUSC	Back pain/ Exacerbation of lower back pain	1	22SEP2020	2/1	1	No	O	NA/TC	R (22SEP2020)	N/N
		GASTR	Diarrhoea/ loose bowel movements	1	24SEP2020	4/2	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C459100 1 1135 11351404	3^	GENRL	Fatigue/ fatigue	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
			Pain/ Body Aches	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		GASTR	Nausea/ nausea	1	14OCT2020	24/1	1	No	O	NA	R (14OCT2020)	N/N
		NERV	Dizziness/ dizziness	1	14OCT2020	24/1	1	No	O	NA	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11135 11351405	3^	GENRL	Chills/ chills	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
			Pain/ body aches	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
			Pyrexia/ fever	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 11135 11351416	3^	GENRL	Injection site pain/ Pain at injection site	1	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
			Chills/ Chills	1	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		GENRL	Pyrexia/ Fever	1	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
			Chills/ chills	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		MUSC	Fatigue/ fatigue	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
			Pyrexia/ fever	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
			Myalgia/ muscle aches	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
			NERV	Headache/ headache	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)
16-55/ C459100	3^	RESP	Nasal congestion/ nasal congestion	1	11OCT2020	19/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1135 11351422	3^	GASTR	Nausea/ nausea	1	15OCT2020	23/C	1	No	O	NA	RG	N/N
1 1135 11351423		NERV	Headache/ headache	1	15OCT2020	23/1	1	No	O	NA	R (15OCT2020)	N/N
		SKIN	Hyperhidrosis/ sweating	1	15OCT2020	23/1	1	No	O	NA	R (15OCT2020)	N/N
16-55/ C459100 1 1135 11351434	3^	BLOOD	Lymphadenopathy/ cervical lymphadenopathy	1	10OCT2020	17/11	1	No	O	NA	R (20OCT2020)	N/N
16-55/ C459100 1 1135 11351435	3^	GENRL	Pyrexia/ fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1135 11351439	3^	RESP	Rhinitis allergic/ Exacerbating allergic rhinitis	1	28SEP2020	4/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1136 11361007	3^	NERV	Migraine/ MIGRAINE HEADACHES*		18AUG2020	1/2	2	Yes		NA	R (19AUG2020)	N/N
16-55/ C459100	3^	INJ&P	Contusion/ BRUISED LEFT ARM	2	24SEP2020	17/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1136 11361012			Contusion/ BRUISED LEFT HIP	2	24SEP2020	17/C	2	No	O	NA/TC	N	N/N
			Contusion/ BRUISED LEFT SHOULDER	2	24SEP2020	17/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1136 11361054	3^	INFEC	Diverticulitis/ WORSENING OF DIVERTICULITIS	2	07OCT2020	20/8	2	No	O	NA	R (14OCT2020)	N/N
16-55/ C459100 1 1139 11391015	2^	GASTR	Abdominal pain/ Abdominal Pain	2	28AUG2020	8/7	1	No	O	NA	R (03SEP2020)	N/N
16-55/ C459100 1 1139 11391037	3^	GENRL	Injection site bruising/ Bruising at injection site	1	04AUG2020	1/9	1	Yes		NA	R (12AUG2020)	N/N
16-55/ C459100 1 1139 11391041	3^	RESP	Dyspnoea/ Incomplete Breaths on Inspiration	2	08SEP2020	16/18	2	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1139 11391071	3^	REPRO	Prostatitis/ Acute prostatitis	2	01SEP2020	5/C	3	No	O	NA/TC/TCN	RG	N/N
		INFEC	Urinary tract infection/ Urinary tract infection	2	03SEP2020	7/C	2	No	O	NA/TC	RG	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11139 11391089	3 [^]	MUSC	Musculoskeletal discomfort/ Left Shoulder discomfort	1	26AUG2020	15/12	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 11139 11391090	3 [^]	GASTR	Abdominal pain/ Abdominal pain	1	12AUG2020	1/4	2	Yes		NA	R (15AUG2020)	N/N
		MUSC	Arthralgia/ Joint Pain	2	05SEP2020	2/C	2	Yes		NA/TC	RG	N/N
		NERV	Headache/ Intermittent Headaches	2	27SEP2020	24/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 11140 11401009	3 [^]	GENRL	Injection site pain/ Injection Site Pain	1	31JUL2020	1/2	1	Yes		NA	R (01AUG2020)	N/N
			Injection site swelling/ Injection Site Swelling	1	31JUL2020	1/2	2	Yes		NA	R (01AUG2020)	N/N
		IMMUN	Anaphylactic reaction/ Anaphylaxis Status Post Bee Sting	2	28AUG2020	9/1	4	No	O	NA/TC	R (28AUG2020)	Y/N
		INFEC	Infected bite/ Cellulitis Status Post Bee Sting	2	30AUG2020	11/11	2	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C459100 11140 11401016	3 [^]	MUSC	Myalgia/ Myalgia	1	31JUL2020	1/2	2	Yes		NA	R (01AUG2020)	N/N
		GASTR	Nausea/ nausea	2	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11140 11401021	3^	PSYCH	Insomnia/ Insomnia	2	12SEP2020	19/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 11140 11401050	3^	GASTR	Diarrhoea/ Diarrhea	1	17AUG2020	13/1	1	Yes		NA	R (17AUG2020)	N/N
16-55/ C459100 11140 11401124	3^	VASC	Hypertension/ hypertension	1	21AUG2020	8/C	2	No	O	NA/TC	N	N/N
		MUSC	Myalgia/ Generalized Muscle Aches	1	24AUG2020	11/7	2	No	O	NA	R (30AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	26AUG2020	13/5	2	No	O	NA	R (30AUG2020)	N/N
		RESP	Upper-airway cough syndrome/ Post-nasal Drip	1	27AUG2020	14/8	1	No	O	NA	R (03SEP2020)	N/N
16-55/ C459100 11140 11401144	3^	GENRL	Injection site pain/ Pain at Injection Site*		04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Injection site pain/ Pain at Injection Site	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ pain at injection site	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11140 11401149		GENRL	Chills/ chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Fatigue/ fatigue	2	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Myalgia/ myalgias	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 11140 11401153	3^	GENRL	Chills/ Chills	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11140 11401160	3^	GENRL	Chills/ chills	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ headache	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 11140 11401177	3^	GENRL	Fatigue/ Fatigue	1	21AUG2020	1/C	1	No	O	NA	N	N/N
16-55/ C459100 11140 11401184	3^	EAR	Hyperacusis/ Increased Sense of Hearing	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GASTR	Dyspepsia/ Heartburn	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N
			Nausea/ Nausea	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N
		NERV	Dizziness/ Lightheadedness	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N
			Parosmia/ Increased Sense of Smell	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N
		PSYCH	Anxiety/ Anxiety	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N
16-55/ C459100 11140 11401198	3^	MUSC	Myalgia/ muscle aches	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 11140 11401203	3^	GENRL	Pyrexia/ Fever	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11140 11401206	3^	NERV	Headache/ Headache	1	27AUG2020	1/1	2	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 11140 11401209	3^	GENRL	Malaise/ General Malaise	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100	3^	GASTR	Nausea/ Nausea	1	30AUG2020	3/1	1	No	O	NA	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1140 11401214			Vomiting/ Vomitting	1	30AUG2020	3/1	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C459100 1 1140 11401219	3^	NERV	Hypoaesthesia/ jaw numbness	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1140 11401224	3^	GENRL	Chills/ Chills	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1140 11401243	3^	GENRL	Chills/ Chills	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1140 11401249	3^	GENRL	Injection site pain/ Pain at injection site	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1140 11401252	3^	GENRL	Fatigue/ fatigue	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Arthralgia/ joint pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	24SEP2020	1/3	3	Yes		NA/TC	R (26SEP2020)	N/N
		GASTR	Diarrhoea/ diarrhea	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
			Nausea/ nausea	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Vomiting/ vomiting	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 11141 11411005	3^	NEOPL	Fibroadenoma of breast/ Left breast fibroadenoma	2	10SEP2020	21/1	2	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C459100 11141 11411006	3^	MUSC	Back pain/ Back Pain	1	31JUL2020	1/10	3	Yes		NA/TC	R (09AUG2020)	N/N
16-55/ C459100 11141 11411008	3^	GENRL	Injection site pain/ injection site pain	1	31JUL2020	1/26	3	Yes		NA	R (25AUG2020)	N/N
		MUSC	Tendonitis/ Shoulder tendonitis	1	31JUL2020	1/C	1	Yes		NA	N	N/N
16-55/ C459100 11141 11411010	3^	PSYCH	Anxiety/ Anxiousness	2	14SEP2020	14/C	2	No	O	NA/TCN	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Depressed mood/ Low Mood	2	14SEP2020	14/C	2	No	O	NA/TCN	N	N/N
16-55/ C459100 11141 11411012	3^	GENRL	Vessel puncture site pain/ pinching sensation in left lower arm after blood draw*		31JUL2020	1/38	1	No	O	NA	R (06SEP2020)	N/N
			Vessel puncture site paraesthesia/ Tingling on lower left arm at blood draw site.*		31JUL2020	1/20	1	No	O	NA	R (19AUG2020)	N/N
16-55/ C459100 11141 11411021	3^	GENRL	Injection site pain/ muscle soreness injection area	2	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
16-55/ C459100 11141 11411023	3^	GENRL	Inflammation/ acute bilateral hand inflammation	1	AUG2020	1/C	2	No	O	NA	RG	N/N
		NERV	Paraesthesia/ Tingling sensation left hand	1	10AUG2020	7/C	1	No	O	NA	RG	N/N
16-55/ C459100 11141 11411024	3^	GASTR	Gastroesophageal reflux disease/ Stomach Reflux	2	12SEP2020	17/C	1	No	O	NA/TC	N	N/N
		RESP	Rhinitis allergic/ Nasal allergies	2	12SEP2020	17/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 11141 11411029	3^	MUSC	Arthralgia/ Arthralgias	2	17SEP2020	23/12	2	Yes		NA/TC/TCN	R (28SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		PSYCH	Anxiety/ Anxiety Flare up	2	18SEP2020	24/C	1	Yes		NA/TC/TCN	N	N/N
16-55/ C459100 11141 11411030	3^	MUSC	Arthralgia/ right wrist pain	2	19SEP2020	25/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 11141 11411046	3^	EAR	Tympanic membrane perforation/ Perforated ear drum right ear	2	27AUG2020	2/14	2	Yes		NA/TC	R (09SEP2020)	N/N
		INFEC	Otitis media acute/ Acute Otitis media	2	27AUG2020	2/14	2	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C459100 11141 11411048	3^	INJ&P	Ankle fracture/ left bimalleolar fracture	1	22AUG2020	16/C	3	No	O	NA/TC	RG	N/N
			Fall/ Fall	1	22AUG2020	16/C	3	No	O	NA/TC	RG	N/N
16-55/ C459100 11141 11411050	3^	GASTR	Diverticulum/ Diverticulosis	2	14SEP2020	19/C	1	No	O	NA	N	N/N
			Large intestine polyp/ colon polyp	2	14SEP2020	19/1	1	No	O	NA/TC	R (14SEP2020)	N/N
16-55/ C459100 11141 11411056	3^	GENRL	Injection site hyperaesthesia/ Hyperesthesia left deltoid region on injection site	2	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411067	3 [^]	MUSC	Plantar fasciitis/ worsening of plantar fasciitis left foot	2	14SEP2020	13/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 11141 11411077	3 [^]	GENRL	Injection site pain/ Post Injection Upper Arm Pain	2	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site bruising/ Injection Site Bruise	2	10SEP2020	2/12	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 11141 11411079	3 [^]	PSYCH	Gastrointestinal somatic symptom disorder/ Stress related gastroesophageal reflux	1	21AUG2020	8/31	1	No	O	NA/TC/TCN	R (20SEP2020)	N/N
16-55/ C459100 11141 11411084	3 [^]	INJ&P	Chest injury/ trauma left rib cage	2	09SEP2020	8/8	1	No	O	NA/TC/TCN	R (16SEP2020)	N/N
16-55/ C459100 11141 11411087	3 [^]	GENRL	Chills/ Chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11141 11411089	3 [^]	MUSC	Myalgia/ myalgia low back	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
		NERV	Headache/ Post vaccination headache	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411092	3^	GENRL	Injection site pain/ Injection Site Pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Pain/ Body Aches	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
		VASC	Flushing/ Facial Flushing	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		CARD	Tachycardia/ tachycardia	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11141 11411096	3^	INV	Body temperature increased/ Elevated Body Temperature	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
		INJ&P	Arthropod bite/ Insect bite left ankle	1	31AUG2020	14/16	2	No	O	NA/TC	R (15SEP2020)	N/N
		SKIN	Erythema/ Erythema left ankle	1	31AUG2020	14/16	2	No	O	NA/TC	R (15SEP2020)	N/N
16-55/ C459100 11141 11411102	3^	GENRL	Injection site pain/ injection site pain	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
		NERV	Headache/ headache	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		CARD	Tachycardia/ tachycardia	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Dizziness/ lightheadedness	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 11141 11411104	3^	INJ&P	Ligament sprain/ Sprained L Ankle	2	07OCT2020	30/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 11141 11411106	3^	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/4	2	Yes		NA/TC/TCN	R (23AUG2020)	N/N
		NERV	Nerve compression/ Pinched nerve right leg	1	26AUG2020	8/C	2	No	O	NA/TC/TCN	RG	N/N
		GENRL	Injection site pain/ Left Arm Pain at injection site	1	11SEP2020	24/3	1	Yes		NA/TC/TCN	R (13SEP2020)	N/N
16-55/ C459100 11141 11411108	3^	GENRL	Fatigue/ Fatigue	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Pain/ Body Aches	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		NERV	Dizziness/ Lightheadedness	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100	3^	NERV	Headache/ Headache, worsening	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1114111411110	3^	GENRL	Injection site pain/ injection site pain	2	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
111411113		UNC	SWOLLEN AXILLARY LYMPH NODE@@/ swollen axillary lymph node	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
16-55/C459100 111411114	3^	GENRL	Injection site pain/ injection site tenderness	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site Soreness	2	11SEP2020	1/5	2	Yes		NA/TC	R (15SEP2020)	N/N
		NERV	Headache/ Headache	2	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
		GENRL	Pain/ Body Aches	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
16-55/C459100 111411119	3^	GENRL	Injection site pain/ Injection Pain	1	21AUG2020	1/3	2	Yes		NA/TC	R (23AUG2020)	N/N
16-55/C459100 111411120	3^	GASTR	Nausea/ nausea	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Asthenia/ generalized weakness	2	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1141 11411121	3^	GENRL	Chills/ chills	2	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N	
			INV	Body temperature increased/ elevated body temperature	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
			GENRL	Injection site induration/ induration at injection Site	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
			GENRL	Injection site pain/ Pain at injection Site	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
			GASTR	Nausea/ Nausea	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
			GENRL	Pain/ Body Aches	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1141 11411122	3^	IMMUN	Headache/ Headache	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N	
			GENRL	Seasonal allergy/ Exacerbation of seasonal allergies	2	21SEP2020	8/7	1	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C459100 1 1141 11411127	3^	RESP	Nasal congestion/ nasal congestion	2	21SEP2020	8/7	1	No	O	NA/TC	R (27SEP2020)	N/N	
		GENRL	Injection site pain/ injection site pain	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N	
		CARD	Tachycardia/ Tachycardia	1	31AUG2020	8/C	2	No	O	NA	N	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411130	3^	GENRL	Injection site pain/ injection site pain	1	25AUG2020	1/5	2	Yes		NA/TCN	R (29AUG2020)	N/N
			Pyrexia/ low grade fever	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain Left Arm	2	15SEP2020	1/5	2	Yes		NA	R (19SEP2020)	N/N
		INV	Body temperature increased/ Elevated Body Temperature	2	15SEP2020	1/3	2	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	2	16SEP2020	2/2	2	Yes		NA/TC/TCN	R (17SEP2020)	N/N
16-55/ C459100 11141 11411131	3^	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain Right Arm	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 11141 11411135	3^	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
		MUSC	Myalgia/ Body Muscle Aches	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411136	3^	INV	Body temperature increased/ Elevated Body Temperature	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site PAin	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	17SEP2020	4/4	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	17SEP2020	4/4	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain Left Arm	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	19SEP2020	3/1	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ arm pain at injection site	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 11141 11411148	3^	GENRL	Injection site pain/ injection site pain left arm	2	18SEP2020	1/4	2	Yes		NA	R (21SEP2020)	N/N
		GENRL	Pain/ body aches	2	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411151	3^	INV	Body temperature increased/ elevated body temperature, max temp 99.8	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ headache	2	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
		GENRL	Pyrexia/ low grade fever	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		MUSC	Myalgia/ whole body myalgia	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 11141 11411153	3^	NERV	Dizziness/ Lightheadedness	2	02OCT2020	12/C	3	No	O	NA/TC	RG	N/N
16-55/ C459100 11141 11411154	3^	GENRL	Tachycardia/ Tachycardia	2	03OCT2020	13/C	3	No	O	NA/TC	RG	N/N
16-55/ C459100 11141 11411154	3^	GENRL	Injection site pain/ injection site pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 11141 11411156	3^	NERV	Headache/ headache	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
		INV	Body temperature increased/ Elevated Body Temperature	1	20SEP2020	21/4	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1141 11411159	3^	MUSC	Arthralgia/ Joint Pain (Neck, Bilateral Hands)	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Hyperaesthesia/ bilateral hand increased sensation to touch	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain left arm	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Chills/ chills	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Pain/ body aches	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ headache	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
		RESP	Dyspnoea exertional/ shortness of breathe while exercising	1	21SEP2020	20/17	1	No	O	NA/TC	R (07OCT2020)	N/N
		NERV	Dizziness/ Lightheadedness	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	16OCT2020	24/C	2	No	O	NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411163	3^	MUSC	Arthralgia/ Worsening bilateral knee pain (persistent)	1	SEP2020	1/C	2	No	O	NA	N	N/N
		GENRL	Injection site pain/ Injection site pain	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain left arm	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
		INV	Body temperature increased/ elevated body temperature, temp. max 99.7	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 11141 11411164	3^	GENRL	Injection site pain/ Injection pain left arm.	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		MUSC	Tendonitis/ tendonitis left arm	1	02SEP2020	1/C	1	Yes		NA	RG	N/N
16-55/ C459100 11141 11411166	3^	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/3	2	Yes		NA/TC	R (04SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
		INV	Body temperature increased/ Elevated body temperature	2	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411167	3^	GENRL	Injection site pain/ Injection site pain.	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Fatigue/ Fatigue	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
		INV	Body temperature increased/ Elevated Body Temperature	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ Muscle Pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		SKIN	Hyperhidrosis/ Sweating	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 11141 11411169	3^	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 11141 11411171	3^	GENRL	Injection site pain/ injection pain left upper arm	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain	1	20SEP2020	18/6	2	Yes		NA	R (25SEP2020)	N/N
		GASTR	Abdominal pain upper/ gastralgia	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	23SEP2020	2/C	2	Yes		NA	RS	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411173	3^	INV	Body temperature increased/ elevated body temperature	2	23SEP2020	2/3	2	Yes		NA	R (25SEP2020)	N/N
		MUSC	Back pain/ back pain	2	23SEP2020	2/3	2	Yes		NA	R (25SEP2020)	N/N
		NERV	Dizziness/ dizziness	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
		RESP	Nasal congestion/ nasal congestion	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 11141 11411174	3^	GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Chills/ chills	2	25SEP2020	1/3	3	Yes		NA/TC	R (27SEP2020)	N/N
			Fatigue/ fatigue	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 11141 11411177	3^		Pain/ body aches	2	25SEP2020	1/3	3	Yes		NA/TC	R (27SEP2020)	N/N
		INV	Body temperature increased/ elevated body temperature, max temp 99.0	2	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
		INV	Body temperature increased/ Elevated Body Temperature	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411179	3^	GENRL	Injection site pain/ Injection Site Soreness	2	25SEP2020	2/4	2	Yes		NA/TC	R (28SEP2020)	N/N
		MUSC	Arthralgia/ Bilateral Knee Arthralgia	2	25SEP2020	2/4	1	Yes		NA/TC	R (28SEP2020)	N/N
			Back pain/ Back Ache	2	25SEP2020	2/4	1	Yes		NA/TC	R (28SEP2020)	N/N
		GENRL	Injection site erythema/ Erythema at Injection Site	2	26SEP2020	3/3	1	Yes		NA	R (28SEP2020)	N/N
		GENRL	Injection site swelling/ Swelling at the Injection Site	2	27SEP2020	4/2	1	Yes		NA	R (28SEP2020)	N/N
		GENRL	Injection site pain/ muscle soreness injection arm	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		NERV	Headache/ Headaches	1	14SEP2020	7/11	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ injection site soreness	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		BLOOD	Lymph node pain/ tender left lymph node axillary	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		INV	Body temperature increased/ elevated body temperature, max temp 103.3	2	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 11141 11411181	3^	GENRL	Injection site pain/ Left arm injection site Pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100	3^	MUSC	Back pain/ back pain	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1114111411182		INFECTION	Vaginal infection/ Vaginal Infection	1	17SEP2020	10/8	1	No	O	NA/TC	R (24SEP2020)	N/N
16-55/ C459100 111411184	3^	NERVOUS	Headache/ Headaches	1	25SEP2020	17/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 111411185	3^	GENERAL	Chills/ Chills	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Fatigue/ Fatigue	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
			Injection site swelling/ Injection Site Swelling	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Pain/ Body Aches	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
		MUSCULOSKELETAL	Myalgia/ Muscle Soreness	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
		GENERAL	Chills/ Chills	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
			Fatigue/ Fatigue	2	29SEP2020	2/3	2	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ Injection Site Pain	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
		MUSCULOSKELETAL	Myalgia/ Muscle Aches	2	29SEP2020	2/3	2	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411186	3^	NERV	Headache/ Headache	1	10SEP2020	2/5	2	Yes		NA/TC	R (14SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ Injection Site Soreness Left Arm	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	2/3	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 11141 11411187	3^	GENRL	Injection site swelling/ Injection site swelling	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	02OCT2020	2/1	2	Yes		NA/TC	R (02OCT2020)	N/N
		NERV	Headache/ Headache	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 11141 11411188	3^	GENRL	Injection site pain/ injection site soreness	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
		MUSC	Myalgia/ Generalized Myalgia	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1141 11411192			Injection site pain/ Injection site pain left arm deltoid	1	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ Headache	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		INV	Body temperature increased/ Elevated body Temperature	1	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
			Injection site pain/ Injection Site Pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
			Pyrexia/ Fever	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		NERV	Headache/ Headache	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1141 11411194	3^	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N
			Injection site pain/ injection site pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ Headache	1	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 11141 11411195	3^	INFEC	Sinusitis/ Sinus Infection	1	30SEP2020	21/10	2	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C459100 11141 11411197	3^	GENRL	Fatigue/ fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ injection site pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 11141 11411198	3^	GENRL	Injection site pain/ Injection site pain	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
			Injection site swelling/ swelling injection area	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Chills/ Chills	2	01OCT2020	2/3	2	Yes		NA/TC	R (03OCT2020)	N/N
			Injection site pain/ Injection Site Pain	2	01OCT2020	2/5	2	Yes		NA	R (05OCT2020)	N/N
		INV	Body temperature increased/ Elevated Body Temperature	2	01OCT2020	2/3	1	Yes		NA/TC	R (03OCT2020)	N/N
		MUSC	Arthralgia/ Joint Pain	2	01OCT2020	2/4	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site erythema/ Erythema at Injection Site	2	04OCT2020	5/4	2	Yes		NA	R (07OCT2020)	N/N
			Injection site macule/ Skin Macule at Injection Site	2	04OCT2020	5/4	2	Yes		NA	R (07OCT2020)	N/N
			Injection site swelling/ Swelling at Injection Site	2	04OCT2020	5/4	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1141 11411202	3^	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/Y
		GENRL	Fatigue/ Fatigue	1	14SEP2020	4/11	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
			Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1141 11411203	3^	GENRL	Injection site pain/ Injection site pain left extremity	1	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N
		INV	Body temperature increased/ Elevated body temperature	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
			Injection site pain/ injection site pain	1	30SEP2020	20/3	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ Injection Site Pain left arm	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1141 11411205	3^	GENRL										

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411209	3^	GENRL	Fatigue/ Fatigue	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ Headache	1	15SEP2020	2/3	2	Yes		NA/TC	R (17SEP2020)	N/N
		NERV	Headache/ headache	1	29SEP2020	16/2	1	No	O	NA/TC	R (30SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		NERV	Headache/ headache	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	07OCT2020	1/3	2	Yes		NA	R (09OCT2020)	N/N
		GENRL	Pyrexia/ low grade fever, max temp 99.9	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	15SEP2020	1/4	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site bruising/ Bruise at Injection Site	1	16SEP2020	2/6	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 11141 11411212	3^	GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	1/4	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Pain/ Body Aches	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
		GENRL		2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411213	3^	GENRL	Injection site pain/ injection site pain left upper arm	1	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ Fever	1	16SEP2020	2/1	2	Yes		NA/TC	R (16SEP2020)	N/N
		MUSC	Arthralgia/ Joint Pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
			Myalgia/ Muscle Pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		GASTR	Tooth impacted/ Impacted Wisdom Teeth	2	16OCT2020	4/1	2	No	O	NA/TC/TCN	R (16OCT2020)	N/N
16-55/ C459100 11141 11411214	3^	INV	Body temperature increased/ elevated body temperature, max temp 99.3	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ headache	2	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
		PSYCH	Mental fatigue/ Mental fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ fatigue	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1141 11411215	3^	GENRL	Fatigue/ fatigue	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
1 1141 11411217			Injection site pain/ injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
			Injection site pain/ injection site pain	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
			Pyrexia/ low grade fever	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		INV	Body temperature increased/ elevated body temperature, temperature 100.4	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
		MUSC	Muscular weakness/ muscle weakness	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1141 11411218	3^	GENRL	Injection site erythema/ Injection site erythema	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection site myalgia	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		METAB	Decreased appetite/ Loss of Appetite	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411219	3^	GENRL	Injection site pain/ injection site soreness	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Soreness Right Arm	1	16SEP2020	1/3	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 11141 11411220	3^	GENRL	Injection site warmth/ Warm Sensation at Injection Site	2	08OCT2020	1/1	1	Yes		NA/TC	R (08OCT2020)	N/N
		VASC	Flushing/ General Flushing	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain left arm	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/Y
		GENRL	Chills/ Chills	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 11141 11411222	3^		Pain/ Body aches	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
			Pain/ Body Aches	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	11OCT2020	3/3	1	Yes		NA	R (13OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411223	3^	MUSC	Arthralgia/ Arthralgia, Bilateral Knees	1	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N
			Myalgia/ Myalgia	1	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N
		UNC	FATIGUE@@/ Fatigue	2	06OCT2020	2/2	1			NA	R (07OCT2020)	N/N
			INJECTION SITE SORENESS@@/ Injection Site Soreness	2	06OCT2020	2/2	1			NA	R (07OCT2020)	N/N
			MYALGIA@@/ Myalgia	2	06OCT2020	2/2	1			NA/TC	R (07OCT2020)	N/N
			Injection site pain/ Injection Site Soreness	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			NERV	Headache/ Headache	1	17SEP2020	2/7	1	Yes		NA/TC	R (23SEP2020)
16-55/ C459100 11141 11411224	3^	GENRL	Injection site pain/ Injection Site Soreness	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 11141 11411226	3^	GENRL	Injection site pain/ Injection Site Pain	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411227	3^	GENRL	Injection site pain/ Pain at injection site left arm	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/Y
		GENRL	Fatigue/ Fatigue	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
		PSYCH	Anxiety/ Worsening anxiety	1	18SEP2020	2/4	1	Yes		NA/TC	R (21SEP2020)	N/N
			Depression/ Worsening depression	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Injection site pain/ Pain at Injection Site	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/Y
		MUSC	Myalgia/ Generalized Myalgias	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
		PSYCH	Depression/ Worsening depression	2	24OCT2020	16/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 11141 11411230	3^	GENRL	Injection site pain/ injection site soreness left arm	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	1	18SEP2020	1/14	1	Yes		NA	R (01OCT2020)	N/N
		INV	Body temperature increased/ elevated body temperature, temperature 99.1	1	20SEP2020	3/1	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411231	3 [^]	BLOOD	Lymphadenopathy/ enlarged left interior neck lymph node	1	30SEP2020	13/C	1	Yes		NA	N	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	16OCT2020	29/4	1	Yes		NA	R (19OCT2020)	N/N
		MUSC	Back pain/ Myalgia in Entire Back	2	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N
		GENRL	Back pain/ Right Sided Upper Back Pain	2	17OCT2020	2/1	2	No	O	NA	R (17OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain Right Arm	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		GENRL	Injection site pain/ injection site soreness	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		NERV	Paraesthesia/ Facial Tingling	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain Left Arm	1	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
GENRL	Injection site erythema/ Erythema at Injection Site	2	10OCT2020	2/5	1	Yes		NA	R (14OCT2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411237	3^	GENRL	Injection site pain/ Injection Site Pain	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
			Fatigue/ Fatigue	1	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 11141 11411240	3^	GENRL	Injection site pain/ Injection Site Pain Left Arm	1	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N
			Injection site swelling/ Swelling at Injection Site	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 11141 11411241	3^	IMMUN	Seasonal allergy/ Seasonal Allergies	1	01OCT2020	10/C	1	No	O	NA/TC	RG	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection Site Pain	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
		INV	Body temperature increased/ body temperature increased	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		MUSC	Myalgia/ Generalized Myalgias	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		NERV	Headache/ Headache	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C459100	3^	INFEC	Puncture site infection/ infected ear piercing right ear	2	27OCT2020	13/12	1	No	O	NA/TC	R (07NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1141 11411242	3^	GENRL	Injection site pain/ Injection Site Pain Left Arm	1	24SEP2020	1/3	2	Yes		NA/TC	R (26SEP2020)	N/N
1 1141 11411243		GENRL	Fatigue/ Fatigue	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		INV	Body temperature increased/ Elevated Body Temperature	1	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Axillary pain/ Left Sided Axilla Pain	2	15OCT2020	2/4	1	Yes		NA	R (18OCT2020)	N/N
		MUSC	Neck pain/ L Sided Cervical Pain	2	15OCT2020	2/5	1	Yes		NA	R (19OCT2020)	N/N
16-55/ C459100 1 1141 11411246	3^	GENRL	Injection site pain/ Injection Site Pain Right Arm	1	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
			Pain/ Body Aches	1	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
		GENRL	Injection site pain/ injection site soreness	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ fatigue	1	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11141 11411247 16-55/ C459100 11141 11411249	3^	GENRL	Injection site pain/ Injection site myalgia left arm	1	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
		GENRL	Injection site swelling/ Swelling at Injection Site Left Arm	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
			Injection site warmth/ Warm Sensation at injection site left Arm	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		GENRL	Injection site erythema/ Erythema at Injection Site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
			Injection site swelling/ Swelling at Injection Site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
			Injection site warmth/ Warmth at Injection Site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Musculoskeletal stiffness/ L Upper Arm Stiffness	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
		GENRL	Feeling cold/ Feeling Cold	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
		MUSC	Arthralgia/ L Sided Shoulder Pain	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
			Neck pain/ L Sided Neck Pain	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
		NERV	Dizziness/ Lightheaded	2	14OCT2020	2/1	2	Yes		NA/TCN	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411250	3^	GENRL	Fatigue/ Fatigue after blood draw*		05OCT2020	1/1	1	No	O	NA	R (05OCT2020)	N/N
16-55/ C459100 11141 11411255	3^	GENRL	Injection site pain/ injection site pain left arm	1	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/Y
16-55/ C459100 11142 11421052	3^	SKIN	Rash/ rash	1	18AUG2020	13/8	2	No	O	NA/TC	R (25AUG2020)	N/N
16-55/ C459100 11142 11421084	3^	INJ&P	Craniocerebral injury/ Closed head injury	1	19AUG2020	8/1	3	No	O	NA	R (19AUG2020)	N/N
		PSYCH	Suicidal ideation/ Suicidal Ideation	1	19AUG2020	8/3	4	No	O	NA/TC	R (21AUG2020)	Y/N
16-55/ C459100 11142 11421158	3^	GENRL	Axillary pain/ left axillary pain	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 11142 11421161	3^	GENRL	Injection site erythema/ Redness at injection site	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ Soreness at injection site	2	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ injection site pain	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1142 11421173		GENRL	Injection site pain/ injection site pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/Y
		GENRL	Injection site bruising/ injection site bruising	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1142 11421202	3^	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1142 11421219	3^	GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
			Pain/ Body aches	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1142 11421222	3^	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
		GENRL	Chills/ Chills	2	06OCT2020	2/3	2	Yes		NA	R (08OCT2020)	N/N
		SKIN	Rash/ Rash on neck	2	06OCT2020	2/4	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11142 11421230	3^	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
11142 11421231		GENRL	Malaise/ Malaise	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 11142 11421231	3^	GENRL	Injection site pain/ Injection Site Pain	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 11142 11421233			Pain/ Body aches	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 11142 11421235	3^	GENRL	Injection site pain/ injection site (left deltoid) soreness	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ injection site (left deltoid) soreness	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 11142 11421248	3^	GENRL	Injection site pain/ injection site (left deltoid) soreness	1	21SEP2020	1/4	2	Yes		NA/TCN	R (24SEP2020)	N/N
		SKIN	Hyperhidrosis/ profuse sweating	2	13OCT2020	1/2	2	Yes		NA/TC	R (14OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1142 11421250	3^	MUSC	Muscular weakness/ muscle weakness	2	14OCT2020	2/2	2	Yes		NA/TC	R (15OCT2020)	N/N
		GENRL	Injection site erythema/ injection site redness	2	16OCT2020	4/2	2	Yes		NA/TC	R (17OCT2020)	N/N
		GENRL	Injection site pruritus/ injection site itching	2	16OCT2020	4/2	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 1142 11421253	3^	GENRL	Injection site erythema/ Redness at injection site	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1142 11421253	3^	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ Headache	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1142 11421258	3^	NERV	Headache/ Headache	2	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
		GENRL	Malaise/ Malaise	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1145 11451017	3^	GENRL	Fatigue/ fatigue	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11145 11451019	3^	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	08SEP2020	1/2	3	Yes		NA	R (09SEP2020)	N/N
			Injection site pain/ Injection site pain	2	08SEP2020	1/6	3	Yes		NA	R (13SEP2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Aches	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Headache	2	08SEP2020	1/3	3	Yes		NA	R (10SEP2020)	N/N
		MUSC	Arthralgia/ Joint pain	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11145 11451022	3^	GENRL	Chills/ Chills	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
			Fatigue/ Fatigue	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
			Injection site pain/ Injection site pain	1	18AUG2020	1/3	2	Yes		NA/TC	R (20AUG2020)	N/N
16-55/ C459100 11145 11451025	3^	GENRL	Fatigue/ Fatigue	1	19AUG2020	2/2	3	Yes		NA	R (20AUG2020)	N/N
			Injection site pain/ Injection site pain	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1145 11451026	3^	NERV	Headache/ Headache	1	19AUG2020	2/2	2	Yes		NA	R (20AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	18AUG2020	1/1	1	Yes		NA	R (18AUG2020)	N/Y
		GENRL	Injection site swelling/ injection site swelling	2	11SEP2020	3/7	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1145 11451030	3^	IMMUN	Seasonal allergy/ worsening of seasonal allergies	2	28SEP2020	20/2	1	No	O	NA	R (29SEP2020)	N/N
		GENRL	Chills/ chills	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
		MUSC	Myalgia/ muscle aches	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C459100 1 1145 11451031	3^	NERV	Headache/ headache	1	22AUG2020	2/1	2	Yes		NA	R (22AUG2020)	N/N
		MUSC	Myalgia/ muscle aches	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
			Pain in extremity/ left arm pain	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ headache	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		RESP	Paranasal sinus discomfort/ Sinus pressure	1	21AUG2020	1/1	1	No	O	NA	R (21AUG2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11145 11451033	3^	GENRL	Fatigue/ Fatigue	1	21AUG2020	1/2	1	No	O	NA	R (22AUG2020)	N/N
		SKIN	Rash/ Rash	1	24AUG2020	4/8	1	No	O	NA	R (31AUG2020)	N/N
16-55/ C459100 11145 11451034	3^	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
		GENRL	Chills/ Chills	2	15SEP2020	1/1	2	Yes		NA	R (15SEP2020)	N/N
			Injection site erythema/ Injection site redness	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ Injection site pain	2	15SEP2020	1/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 11145 11451037	3^	GENRL	Fatigue/ Fatigue	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
		GENRL	Injection site pain/ Arm pain at injection site	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 11145 11451043	3^	GENRL	Injection site pain/ left arm injection site pain	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Injection site pain/ left arm injection site pain	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11145 11451053	3^	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Chills/ Chills	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
			Fatigue/ Fatigue	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
		MUSC	Arthralgia/ Joint pain	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 11145 11451057	3^	GENRL	Injection site pain/ left arm injection site pain	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 11145 11451059	3^	EYE	Photophobia/ Photophobia	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/Y
		GENRL	Injection site pain/ Injection site pain	1	28AUG2020	1/4	2	Yes		NA	R (31AUG2020)	N/Y
		NERV	Headache/ Headache	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/Y
		MUSC	Arthralgia/ Knee pain	1	08SEP2020	12/4	2	No	O	NA	R (11SEP2020)	N/N
		MUSC	Joint swelling/ Knee swelling	1	11SEP2020	15/1	2	No	O	NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11145 11451063	3^	MUSC	Intervertebral disc protrusion/ disc herniation	1	14SEP2020	15/C	2	No	O	NA/TC	RG	N/N
		NERV	Paraesthesia/ Paresthesias of Skin	1	21SEP2020	22/8	3	No	CD	NA/TC	R (28SEP2020)	Y/N
		NERV	Dizziness/ dizziness	1	24SEP2020	25/2	2	No	CD	NA	R (25SEP2020)	N/N
16-55/ C459100 11145 11451064	3^	GENRL	Injection site pain/ pain at injection site	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ fever	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 11145 11451068	3^	GENRL	Injection site pain/ mild pain on injection site in left arm	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 11145 11451071	3^	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/2	2	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Fatigue/ fatigue	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ fever	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1145 11451074	3^	MUSC	Myalgia/ muscle pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 1 1145 11451075	3^	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 1 1145 11451079	3^	NERV	Headache/ Headache	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
		MUSC	Pain in extremity/ Arm pain	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Chills/ chills	2	25SEP2020	2/2	3	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1145 11451080	3^		Pyrexia/ fever	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11145 11451081	3^	GENRL	Injection site pain/ Injection site pain*		09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
		GENRL	Chills/ chills	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ injection site pain	1	29SEP2020	21/2	2	Yes		NA	R (30SEP2020)	N/N
		MUSC	Myalgia/ muscle ache	2	29SEP2020	1/2	3	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 11145 11451086	3^	GASTR	Nausea/ nausea*		09SEP2020	1/23	2	Yes		NA	R (01OCT2020)	N/N
		GENRL	Fatigue/ fatigue	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Injection site pain/ injection site pain	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		RESP	Nasal congestion/ nasal congestion	1	10SEP2020	2/3	1	No	O	NA/TC	R (12SEP2020)	N/N
			Oropharyngeal pain/ sore throat	1	10SEP2020	2/3	1	No	O	NA	R (12SEP2020)	N/N
			Rhinorrhoea/ nasal discharge	1	10SEP2020	2/3	1	No	O	NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ headache	1	29SEP2020	21/3	2	Yes		NA	R (01OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11145 11451088	3^	RESP	Upper-airway cough syndrome/ post nasal drip	2	19OCT2020	21/3	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 11145 11451090	3^	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		SKIN	Drug eruption/ fixed drug eruption	2	01OCT2020	3/9	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 11145 11451091	3^	GENRL	Chills/ chills*		10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
			Injection site pain/ injection site pain*		10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Chills/ chills	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ injection site pain	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
			Pyrexia/ fever	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11145 11451093	3^	GENRL	Chills/ chills	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
		SKIN	Hyperhidrosis/ sweating	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1145 11451107	3^	GENRL	Chills/ chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Fatigue/ fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ injection site pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain left arm	1	18SEP2020	1/4	2	Yes		NA	R (21SEP2020)	N/N
		GENRL	Chills/ shivering	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N
		GENRL	Injection site pain/ left arm injection site pain	1	08OCT2020	21/2	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Pain/ body aches	1	08OCT2020	21/2	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1146 11461002	3^	GASTR	Vomiting/ vomitting	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
		INV	Blood pressure increased/ Elevation of baseline blood pressure	2	15SEP2020	15/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1146 11461007	3^	EYE	Eye irritation/ Burning eyes status post injection #1	1	12AUG2020	1/5	1	Yes		NA	R (16AUG2020)	N/N
		EYE	Eye irritation/ Burning eyes status post injection #2	2	31AUG2020	1/5	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11146 11461021	3^	GENRL	Fatigue/ Fatigue	1	14AUG2020	1/8	2	Yes		NA	R (21AUG2020)	N/N
		NERV	Headache/ Headache	1	14AUG2020	1/8	2	Yes		NA	R (21AUG2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	20AUG2020	7/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C459100 11146 11461044	3^	EYE	Eye pain/ Bilateral eye pain	2	06OCT2020	29/14	1	No	O	NA	R (19OCT2020)	N/N
		INV	Blood pressure increased/ blood pressure elevation	2	20OCT2020	43/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 11146 11461054	3^	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/5	1	Yes		NA	R (23AUG2020)	N/Y
		GENRL	Injection site pain/ Injection sit pain post 2nd injection	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 11146 11461058	3^	GENRL	Injection site pain/ injection site pain left arm	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/Y
16-55/ C459100 11146 11461061	3^	GASTR	Diarrhoea/ Diarrhea	1	20AUG2020	2/5	1	Yes		NA	R (24AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11146 11461075	3^	BLOOD	Lymphadenopathy/ Enlarged lymph node	2	15SEP2020	8/C	1	Yes		NA	N	N/N
		INFECTION	Hordeolum/ sty left eye	2	15SEP2020	8/22	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100 11146 11461085	3^	RESP	Sinus congestion/ Congested Sinuses	2	08NOV2020	59/C	1	No	O	NA	N	N/N
16-55/ C459100 11146 11461092	3^	GASTRO	Diarrhoea/ Diarrhea	1	28AUG2020	8/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 11146 11461124	3^	INJECTION	Post procedural haemorrhage/ Mild nose bleed s/p nasal swab*		27AUG2020	1/1	1	No	O	NA/TCN	R (27AUG2020)	N/N
16-55/ C459100 11146 11461130	3^	MUSCULOSKELETAL	Back pain/ Right mid to low back pain	2	14OCT2020	30/3	1	No	O	NA/TCN	R (16OCT2020)	N/N
16-55/ C459100 11146 11461150	3^	NERVOUS	Headache/ headache- day 8-9 post vaccine	1	05SEP2020	9/3	1	Yes		NA	R (07SEP2020)	N/N
		EYE	Vitreous detachment/ Posterior Vitriol Detachment	2	21SEP2020	6/C	2	No	O	NA	N	N/N
		SKIN	Dermatitis contact/ Poison Ivy Rash	2	08OCT2020	23/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11146 11461170	3^	MUSC	Arthralgia/ Pain in left knee	1	SEP2020	1/C	2	No	O	NA	N	N/N
		GASTR	Food poisoning/ food poisoning	1	15SEP2020	15/2	1	No	O	NA	R (16SEP2020)	N/N
			Nausea/ Nausea	1	15SEP2020	15/2	1	No	O	NA	R (16SEP2020)	N/N
16-55/ C459100 11146 11461176	3^	GENRL	Vaccination site induration/ 6cm induration secondary to flu vaccine	2	06OCT2020	16/5	2	No	CND	NA	R (10OCT2020)	N/N
16-55/ C459100 11146 11461183	3^	GENRL	Chills/ Chills	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
			Pain/ Body aches	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 11146 11461187	3^	INFEC	Herpes simplex/ Herpes Simplex 1	1	14SEP2020	13/8	1	No	O	NA/TC	R (21SEP2020)	N/N
16-55/ C459100 11146 11461197	3^	MUSC	Bursitis/ Bursitis of the knee	1	22SEP2020	20/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 11146 11461200	3^	CARD	Atrioventricular block first degree/ 1 Degree AV block	2	27SEP2020	3/1	2	No	O	NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1146 11461204	3^	NERV	Bradycardia/ Acute Bradycardia	2	27SEP2020	3/2	3	No	O	NA/TC	R (28SEP2020)	Y/N
			Loss of consciousness/ Loss of consciousness	2	27SEP2020	3/3	2	No	O	NA	R (29SEP2020)	Y/N
			Depression/ Worsening of depression	2	13OCT2020	22/14	2	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C459100 1 1146 11461206	3^	RESP	Upper-airway cough syndrome/ Post nasal drip	2	27OCT2020	35/4	1	No	O	NA	R (30OCT2020)	N/N
16-55/ C459100 1 1146 11461212	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	2	07OCT2020	15/8	2	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1146 11461218	3^	INFEC	Hordeolum/ Stye of the left eye	1	23SEP2020	20/8	1	No	O	NA/TCN	R (30SEP2020)	N/N
16-55/ C459100 1 1146 11461219	3^	NERV	Headache/ Mild Headache	1	23SEP2020	20/1	1	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1146 11461237	3^	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/ Injection site pain	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1146 11461238	3^	GENRL	Pain/ Body aches	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
			Chills/ Chills	2	07OCT2020	2/3	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1146 11461239	3^	GENRL	Pain/ Body aches	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
			Pyrexia/ Low grade fever of 100.8	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
			Pain/ Bodyaches	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/Y
			NERV Headache/ Headaches post vaccine #2	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1146 11461241	3^	GENRL	Chills/ Chills	2	07OCT2020	2/3	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1146 11461245	3^	INV	Fatigue/ Fatigue	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
			Injection site pain/ Injection site pain	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
			Blood pressure increased/ Elevated blood pressure	2	02NOV2020	28/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1146 11461248	3^	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ Fever of 101.5 post injection #2	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1146 11461250	3^	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/5	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1146 11461255	3^	GENRL	Chills/ Chills	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
			Fatigue/ Fatigue	2	10OCT2020	2/2	2	Yes		NA	R (11OCT2020)	N/N
			Injection site pain/ Injection site pain	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
		NERV	Headache/ Headache	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C459100 1 1147 11471003	3^	VASC	Essential hypertension/ essential hypertension	2	21AUG2020	3/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1147 11471019	3^	MUSC	Myalgia/ Muscle ache	2	24AUG2020	1/5	3	Yes		NA/TC	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11147 11471047	3^	PSYCH	Anxiety/ Anxiety (New Diagnosis)	2	28AUG2020	3/C	1	No	O	NA/TCN	N	N/N
16-55/ C459100 11147 11471049	3^	INV	Blood thyroid stimulating hormone increased/ elevated TSH	2	18SEP2020	22/C	1	No	O	NA	N	N/N
16-55/ C459100 11147 11471053	3^	NERV	Migraine/ migraine (exacerbation)	2	10OCT2020	44/2	1	No	O	NA	R (11OCT2020)	N/N
16-55/ C459100 11147 11471073	3^	INV	Blood creatinine decreased/ Decreased Creatinine (31.6)	2	02SEP2020	3/C	1	No	O	NA	N	N/N
16-55/ C459100 11147 11471092	3^	RESP	Rhinitis allergic/ Allergic Rhinitis	2	11SEP2020	11/8	1	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C459100 11147 11471112	3^	RESP	Oropharyngeal pain/ Sore throat*		12AUG2020	-12/13	1	No	O	NA	R (24AUG2020)	N/N
16-55/ C459100 11147 11471121	3^	INFEC	Abscess neck/ Nape abscess	2	25SEP2020	22/2	1	No	O	NA/TC	R (26SEP2020)	N/N
16-55/ C459100	3^	INFEC	Influenza/ Flu A&B	2	21SEP2020	12/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1147 11471153	3^	INV	Blood cholesterol increased/ elevated cholesterol	2	06OCT2020	26/C	1	No	O	NA	N	N/N
1 1147 11471166	3^	GENRL	Injection site pain/ Pain at injection site	1	09SEP2020	17/6	1	Yes		NA	R (14SEP2020)	N/N
1 1147 11471180	3^	BLOOD	Anaemia/ anemia (new diagnosis)	1	11SEP2020	9/C	1	No	O	NA/TC	N	N/N
1 1149 11491001	3^	GENRL	Pyrexia/ Fever	2	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N
		MUSC	Pain in extremity/ Pain in left arm	2	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
1 1149 11491012	3^	GASTR	Diarrhoea/ Diarrhea	2	01SEP2020	8/25	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Flank pain/ Flank Pain	2	15SEP2020	22/8	1	No	CND	NA	R (22SEP2020)	N/N
		NERV	Headache/ Headache	2	20SEP2020	27/3	1	No	CND	NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11149 11491020	3^	GENRL	Chills/ chills	2	31AUG2020	5/2	1	Yes		NA	R (01SEP2020)	N/N
			Fatigue/ fatigue	2	31AUG2020	5/2	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C459100 11149 11491025	3^	GENRL	Fatigue/ fatigue	1	08AUG2020	2/3	1	Yes		NA	R (10AUG2020)	N/N
		GENRL	Injection site erythema/ injection site redness	1	12AUG2020	6/2	1	Yes		NA	R (13AUG2020)	N/N
16-55/ C459100 11149 11491044	3^	GASTR	Nausea/ nausea	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site pain/ left arm pain at injection site with touch	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ fever	2	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 11149 11491057	3^	GASTR	Diarrhoea/ loose stool	1	12AUG2020	1/1	1	Yes		NA	R (12AUG2020)	N/N
16-55/ C459100 11149 11491076	3^	MUSC	Pain in extremity/ right arm pain	1	17AUG2020	1/3	2	Yes		NA	R (19AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11149 11491077	3^	GENRL	Chills/ Chills	1	18AUG2020	2/3	1	Yes		NA	R (20AUG2020)	N/N
			Pain/ Body Aches	1	18AUG2020	2/3	1	Yes		NA	R (20AUG2020)	N/N
			Pyrexia/ Fever	1	18AUG2020	2/3	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C459100 11149 11491083	3^	MUSC	Myalgia/ Myalgia	2	09SEP2020	2/28	2	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100 11149 11491086	3^	GENRL	Injection site pain/ left arm pain at injection site related to motion	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
		GENRL	Fatigue/ fatigue	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
			Injection site pain/ left arm pain at injection site related to motion	2	09SEP2020	2/6	1	Yes		NA	R (14SEP2020)	N/N
			Pain/ body aches	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 11149 11491089	3^	GENRL	Injection site pain/ Left arm pain at injection site	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11149 11491092	3^	GASTR	Vomiting/ Emesis	1	06SEP2020	19/31	1	No	O	NA	R (06OCT2020)	N/N
		NERV	Lethargy/ Lethargic	1	23AUG2020	5/1	1	Yes		NA	R (23AUG2020)	N/N
		GENRL	Fatigue/ Tired	1	26AUG2020	8/1	1	Yes		NA	R (26AUG2020)	N/N
	3^	PSYCH	Insomnia/ Difficulty sleeping	1	31AUG2020	13/2	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Fatigue/ Tired	1	01SEP2020	14/1	1	Yes		NA	R (01SEP2020)	N/N
		MUSC	Musculoskeletal pain/ joint/muscle pain in arms and legs	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
		GENRL	Myalgia/ left triceps pain	1	20AUG2020	2/5	1	Yes		NA	R (24AUG2020)	N/N
		GENRL	Injection site pain/ injection site pain with motion	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N
		MUSC	Pain in extremity/ Left arm pain*		20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
3^	MUSC	Myalgia/ Generalized myalgia	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1149 11491121		GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	12SEP2020	2/4	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1149 11491128	3^	MUSC	Pain in extremity/ left arm soreness	1	24AUG2020	1/2	2	Yes		NA/TC	R (25AUG2020)	N/N
16-55/ C459100 1 1149 11491136	3^	MUSC	Myalgia/ left arm muscle pain with motion	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		GASTR	Nausea/ nausea	1	27AUG2020	3/1	1	Yes		NA	R (27AUG2020)	N/N
		NERV	Headache/ headache/ left-post occipital pain	1	27AUG2020	3/1	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 1 1149 11491146	3^	GENRL	Injection site pain/ Left arm injection site pain	1	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
		UNC	LEFT ARM BLEEDING AT INJECTION SITE@@/ Left arm bleeding at injection site	1	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/Y
16-55/ C459100	3^	GASTR	Abdominal discomfort/ Upset stomach	2	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1149 11491157			Diarrhoea/ Diarrhea	2	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1149 11491165	3^	GENRL	Injection site pain/ left arm pain at injection site with movement	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1149 11491176	3^	GENRL	Injection site pain/ Left arm pain at injection site	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 1 1149 11491180	3^	MUSC	Pain in extremity/ left arm pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		NERV	Headache/ headache	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 1 1149 11491181	3^	GENRL	Injection site pain/ Left arm pain at injection site with touch	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 1 1149 11491186	3^	GENRL	Injection site pain/ left arm injection site pain with touch	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
		MUSC	Musculoskeletal chest pain/ muscle chest pain	2	23SEP2020	1/3	1	No	O	NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1149 11491202	3^	GENRL	Chills/ chills	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Arthralgia/ Joint pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 1 1149 11491203	3^		Pain in extremity/ Left arm pain	1	05SEP2020	2/4	1	Yes		NA/TC	R (08SEP2020)	N/N
		GENRL	Chills/ chills	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
			Pain/ body aches	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Pain/ Body aches	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1149 11491210	3^		Pyrexia/ Fever/chills	2	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
		GENRL	Injection site pain/ left arm pain at injection site	1	05SEP2020	2/4	1	Yes		NA	R (08SEP2020)	N/N
		NERV	Headache/ headache	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11149 11491218	3^	GENRL	Chills/ chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
			Fatigue/ fatigue	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
			Injection site pain/ Left arm injection site pain with motion	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
			Pyrexia/ fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ headache	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 11149 11491219	3^	MUSC	Pain in extremity/ Left arm soreness	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
			Fatigue/ Fatigue	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ fatigue	1	09SEP2020	2/4	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1149 11491220			Injection site pain/ left arm pain at injection site	1	09SEP2020	2/4	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1149 11491221	3^	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ Headache	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		GASTR	Paraesthesia oral/ Buccal paresthesia	1	13SEP2020	4/27	1	Yes		NA	R (09OCT2020)	N/N
		MUSC	Musculoskeletal chest pain/ Chest pain (muscular not cardiac)	1	14SEP2020	5/3	3	Yes		NA	R (16SEP2020)	N/N
		GASTR	Gingival pain/ Gingival pain	1	22SEP2020	13/4	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1149 11491227	3^	GENRL	Fatigue/ fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
			Injection site pain/ Left arm injection site pain with motion	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1149 11491234	3^	GENRL	Injection site pain/ Left arm injection pain	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ Low Fever (99.6 F)	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Injection site pain/ Left arm injection site pain with motion	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Pyrexia/ Low Grade Fever (99.6 F)	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1149 11491238	3^	GENRL	Feeling hot/ Hot ears	1	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
			Injection site pain/ left arm pain at injection site	1	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
		RESP	Pharyngeal swelling/ Swelling in throat (no shortness of breath)	1	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1149 11491254	3^	GASTR	Nausea/ Nausea	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ pain in left arm at injection site	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1149 11491258	3^	GENRL	Injection site erythema/ Injection site erythema	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/Y
			Injection site pain/ Pain at injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/Y
16-55/ C459100 1 1149 11491270	3^	GENRL	Injection site pain/ Left arm pain at injection site	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ headache	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1149 11491271	3^	GENRL	Injection site pain/ left arm pain at injection site related to motion	1	28SEP2020	8/8	1	Yes		NA	R (05OCT2020)	N/N
		GENRL	Pyrexia/ fever	2	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
		NERV	Headache/ headache	2	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1149 11491273	3^	GENRL	Fatigue/ fatigue	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1149 11491274	3^	GENRL	Injection site pain/ Left arm injection site pain with touch and movement	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11149 11491275	3^	MUSC	Arthralgia/ Joint pain	2	13OCT2020	1/2	3	Yes		NA	R (14OCT2020)	N/N
			Myalgia/ Myalgia	2	13OCT2020	1/2	3	Yes		NA	R (14OCT2020)	N/N
		GENRL	Injection site pain/ Right arm injection site pain with touch	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ Right arm injection site pain with movement and touch	2	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 11149 11491281	3^	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		GENRL	Injection site pain/ Left arm injection site pain with touch	1	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 11149 11491285	3^		Pyrexia/ Fever	1	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Flank pain/ left flank pain	1	23SEP2020	1/5	1	Yes		NA	R (27SEP2020)	N/N
			Pain in extremity/ Left arm pain	1	23SEP2020	1/5	1	Yes		NA/TC	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11149 11491286	3^	GENRL	Nodule/ hypopigmented nodule lesion right dorsal 2nd metacarpal	1	30SEP2020	8/7	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 11149 11491289	3^	GENRL	Injection site pain/ Left arm pain at injection site	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Chills/ chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 11149 11491294	3^	GENRL	Injection site pain/ left arm injection site pain with touch	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 11149 11491305	3^	GENRL	Injection site pain/ left arm injection site pain with movement	1	24SEP2020	1/22	1	Yes		NA	R (15OCT2020)	N/Y
16-55/ C459100 11149 11491310	3^	GENRL	Chills/ chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
			Pyrexia/ fever	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ headache	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1149 11491311	3^	GENRL	Injection site pain/ left arm injection site pain	1	24SEP2020	1/4	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C459100 1 1149 11491314	3^	GENRL	Injection site pain/ left arm injection site pain	1	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ headache	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1149 11491315	3^	GENRL	Chills/ chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
			Fatigue/ fatigue	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
			Pyrexia/ fever	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1149 11491316	3^	GENRL	Pyrexia/ Fever	1	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ right arm pain at injection site	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
			Pyrexia/ fever	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11150 11501001	3^	MUSC	Myalgia/ General Muscle Pain	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
		GASTR	Pancreatitis/ Worsening Pancreatitis	1	21AUG2020	5/34	3	No	O	NA	R (23SEP2020)	Y/N
16-55/ C459100 11150 11501003	3^	MUSC	Pain in extremity/ Arm Soreness (Left Arm)	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 11150 11501004	3^	RESP	Cough/ cough	1	05SEP2020	20/5	1	No	O	NA	R (09SEP2020)	N/N
			Nasal congestion/ nasal congestion	1	05SEP2020	20/5	1	No	O	NA	R (09SEP2020)	N/N
			Oropharyngeal pain/ sore throat	1	05SEP2020	20/5	1	No	O	NA	R (09SEP2020)	N/N
			Rhinorrhoea/ runny nose	1	05SEP2020	20/5	1	No	O	NA	R (09SEP2020)	N/N
16-55/ C459100 11150 11501005	3^	GENRL	Injection site pain/ arm soreness (injection site, left arm)	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
		GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Pyrexia/ Fever (100.1)	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11150 11501006	3^	MUSC	Pain in extremity/ Arm Soreness (Left arm)	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Pain/ Body Aches	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11150 11501007	3^	GASTR	Pyrexia/ Fever (100.0 F)	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
			Diarrhoea/ Diarrhea	2	15SEP2020	8/1	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C459100 11150 11501009	3^	GASTR	Diarrhoea/ Diarrhea	1	25AUG2020	8/1	1	Yes		NA	R (25AUG2020)	N/N
16-55/ C459100 11150 11501011	3^	RESP	Oropharyngeal pain/ Sore Throat	1	03SEP2020	17/1	1	No	O	NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Arm soreness (injection site,left)	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Pain/ Body Aches	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ Fever (101.5 F)	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11150 11501013	3^	MUSC	Pain in extremity/ Arm pain/soreness (Left arm)	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Arm soreness (injection site, left arm)	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C459100 11150 11501014	3^	GENRL	Fatigue/ Fatigue	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site pain/ Burning sensation at injection site (left arm)	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/Y
16-55/ C459100 11150 11501015	3^	GENRL	Injection site pain/ Pain at injection site	2	12SEP2020	3/3	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C459100 11150 11501016	3^	MUSC	Pain in extremity/ Arm Soreness (Right arm)	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 11150 11501017	3^	NERV	Headache/ Headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Pain in extremity/ Arm Soreness (Left arm)	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 11150 11501018	3^	GENRL	Injection site pain/ Arm soreness (injection site)	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11150 11501019	3^	MUSC	Pain in extremity/ Arm Soreness (Left arm)	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
		MUSC	Myalgia/ muscle aches	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
		GENRL	Chills/ Chills	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Pain/ Body Aches	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 11150 11501020	3^	GENRL	Pyrexia/ Fever	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C459100 11150 11501021	3^	GENRL	Fatigue/ Fatigue	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C459100 11150 11501024	3^	GENRL	Fatigue/ Tiredness	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1150 11501025	3 [^]	GENRL	Injection site pain/ Arm soreness (Injection site left arm)	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
			Chills/ Chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
			Fatigue/ Tiredness	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ Fever (101.5)	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Headache	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Chills/ Chills	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 1 1150 11501027	3 [^]	GENRL	Injection site pain/ Arm soreness (left injection site)	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
		GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Pain in extremity/ Arm Soreness (Left Arm)	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100	3 [^]	GENRL	Injection site pain/ Arm soreness in injection site	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1150 11501029		NERV	Headache/ Headache	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1150 11501032	3^	GENRL	Injection site pain/ pain at injection site	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N
		GENRL	Fatigue/ fatigue	1	25AUG2020	2/5	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
			Fatigue/ Fatigue	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1150 11501036	3^	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1150 11501037	3^	GENRL	Injection site pain/ Arm soreness (injection L site arm)	1	24AUG2020	1/2	2	Yes		NA	R (25AUG2020)	N/N
		GASTR	Nausea/ Nausea	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		MUSC	Pain in extremity/ Arm Soreness (Left arm)	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		BLOOD	Lymphadenopathy/ Swollen lymph nodes under left armpit	2	18SEP2020	5/C	1	No	O	NA	N	N/N
16-55/ C459100 11150 11501039	3^	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	1/2	2	Yes		NA	R (26AUG2020)	N/N
		GENRL	Pain/ Body Aches	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ Fever	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11150 11501040	3^	GENRL	Injection site pain/ pain at injection site	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
		CARD	Supraventricular tachycardia/ Worsening Supraventricular Tachycardia	1	02SEP2020	9/C	2	Yes		NA	RG	N/N
		GENRL	Chills/ Chills	2	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N
			Pain/ Body Aches	2	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ Headache	2	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 11150 11501041	3^	GENRL	Pyrexia/ fever (101.0)	1	11SEP2020	18/1	1	No	O	NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11150 11501043	3^	INJ&P	Concussion/ concussion	1	05SEP2020	12/6	1	No	O	NA	R (10SEP2020)	N/N
			Fall/ Fall from stairs at home	1	05SEP2020	12/1	1	No	O	NA/TCN	R (05SEP2020)	N/N
			Ligament sprain/ ankle sprain (left)	1	05SEP2020	12/4	1	No	O	NA	R (08SEP2020)	N/N
		GENRL	Pain/ Body Aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11150 11501044	3^	GENRL	Injection site pain/ pain at injection site	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Chills/ Chills	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ Pain at injection site (right arm)	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		SKIN	Hyperhidrosis/ Sweats	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11150 11501046	3^	GENRL	Injection site pain/ pain at injection site	1	26AUG2020	2/3	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1150 11501048	3^	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	26AUG2020	2/3	2	Yes		NA	R (28AUG2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/Y
		GENRL	Chills/ Chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1150 11501050	3^	GENRL	Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ Pain at injection Site	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1150 11501051	3^	RESP	Oropharyngeal pain/ Sore Throat	2	01OCT2020	16/3	1	No	O	NA	R (03OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	26AUG2020	1/2	2	Yes		NA	R (27AUG2020)	N/N
		GASTR	Nausea/ Nausea	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		METAB	Decreased appetite/ Loss of Appetite	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11150 11501053	3^	NERV	Tremor/ Body Shakes	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		PSYCH	Insomnia/ Insomnia	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		SKIN	Night sweats/ Night Sweats	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	2	20SEP2020	5/1	2	Yes		NA	R (20SEP2020)	N/N
		GENRL	Injection site pain/ Arm soreness (left arm) injection site	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 11150 11501056	3^	GENRL	Injection site pain/ Arm soreness (Left arm, injection site)	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Fatigue/ Fatigue	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100	3^	NERV	Injection site pain/ Pain at injection site	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
			Headache/ Headache	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100	3^	GASTR	Nausea/ nausea	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1150 11501058		GENRL	Fatigue/ fatigue	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
			Injection site pain/ arm pain: injection site, left arm	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ Arm Pain (Injection Site)	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
			Pain/ Body Aches	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1150 11501059	3^	GENRL	Injection site pain/ pain at injection site	1	27AUG2020	2/4	1	Yes		NA	R (30AUG2020)	N/N
		NERV	Headache/ Headache	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1150 11501060	3^	GENRL	Injection site pain/ arm soreness (injection site), Left arm	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
		GASTR	Nausea/ Nausea	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11150 11501063	3^	GENRL	Vomiting/ Vomiting	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Fatigue/ Fatigue	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		MUSC	Pain in extremity/ Left arm soreness	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		MUSC	Pain in extremity/ Left arm soreness	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 11150 11501064	3^	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Pain/ Body Aches	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ arm soreness (left arm); injection site	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 11150 11501067	3^	GENRL	Injection site pain/ Pain at injection site	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		GASTR	Abdominal pain/ Abdominal Pain	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Chills/ Chills	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1150 11501068	3^	NERV	Fatigue/ Fatigue	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
			Headache/ Headache	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
			Nasal congestion/ Congested Nose	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
			Oropharyngeal pain/ Sore Throat	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
		NERV	Headache/ Headache	2	05OCT2020	19/2	1	No	O	NA	R (06OCT2020)	N/N
		GENRL	Chills/ chills	1	28AUG2020	2/1	2	Yes		NA	R (28AUG2020)	N/N
			Injection site pain/ Pain at injection site	1	28AUG2020	2/2	2	Yes		NA	R (29AUG2020)	N/N
			Pain/ Body aches	1	28AUG2020	2/1	2	Yes		NA	R (28AUG2020)	N/N
		INFEC	Ear infection/ Right ear infection	1	14SEP2020	19/C	2	No	O	NA/TC	RG	N/N
		GENRL	Injection site pain/ Pain at injection site	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N		
16-55/ C459100 1 1150 11501069	3^	GENRL	Injection site pain/ arm soreness (left arm, injection site)	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11150 11501073	3^	GENRL	Injection site pain/ Pain at injection site	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ Headache	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Pyrexia/ low grade fever (99.9)	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		MUSC	Pain in extremity/ arm soreness (left arm)	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		NERV	Headache/ headache	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Chills/ Chills	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 11150 11501075	3^		Pain/ Body Aches	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
			Pyrexia/ Fever	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	31AUG2020	1/3	2	Yes		NA	R (02SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11150 11501077	3^	GENRL	Injection site pain/ Burning sensation at injection site	2	30SEP2020	9/2	1	Yes		NA	R (01OCT2020)	N/N
		GASTR	Diarrhoea/ diarrhea	1	15SEP2020	15/2	1	No	O	NA	R (16SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 11150 11501078	3^	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		GASTR	Nausea/ nausea	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ chills	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
		NERV	Injection site pain/ pain at injection site	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
		NERV	Migraine/ migraine	1	01SEP2020	1/2	3	Yes		NA	R (02SEP2020)	N/N
GENRL	Chills/ Chills	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N		
MUSC	NERV	GENRL	Injection site pain/ Pain at injection site	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1150 11501079	3^	GENRL	Fatigue/ fatigue	1	03SEP2020	3/2	1	Yes		NA	R (04SEP2020)	N/N
		NERV	Dizziness/ dizziness	1	03SEP2020	3/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1150 11501082	3^	GENRL	Pain/ Body Aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
			Pyrexia/ Low grade fever	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ Injection Site Pain	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Pain/ Body Aches	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1150 11501083	3^	GENRL	Injection site pain/ Pain at injection Site*		01SEP2020	1/4	2	Yes		NA	R (04SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	02SEP2020	2/3	2	Yes		NA	R (04SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 11150 11501084	3^	GENRL	Injection site pain/ Pain at injection site	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N	
			Chills/ Chills	1	19SEP2020	19/5	1	No	O	NA	R (23SEP2020)	N/N	
			Headache/ Headache	1	19SEP2020	19/5	1	No	O	NA	R (23SEP2020)	N/N	
			Cough/ Cough	1	19SEP2020	19/5	1	No	O	NA	R (23SEP2020)	N/N	
16-55/ C459100 11150 11501085	3^	GENRL	Oropharyngeal pain/ Sore Throat	1	19SEP2020	19/5	2	No	O	NA	R (23SEP2020)	N/N	
			Chills/ chills	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
			Fatigue/ fatigue	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
			Injection site pain/ arm soreness (left) injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
			NERV	Headache/ headache	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
			GENRL	Fatigue/ Fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			NERV	Pain/ Body Aches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
NERV	Headache/ Headache	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N			

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1150 11501087	3^	GENRL	Injection site pain/ Arm soreness (Right arm, injection site)	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
			Chills/ Chills	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	
			Pain/ Body Aches	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	
			Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N	
16-55/ C459100 1 1150 11501088	3^	GENRL	Fatigue/ fatigue	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
			Injection site pain/ left arm pain (injection site)	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
			Insomnia/ trouble sleeping	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
			Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N	
16-55/ C459100 1 1150 11501089	3^	GASTR	Nausea/ nausea	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
			GENRL	Fatigue/ fatigue	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
			PSYCH	Irritability/ irritable mood	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1150 11501090	3^	GASTR	Abdominal pain upper/ Stomach Pain	2	24SEP2020	2/C	1	Yes		NA	RG	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	3	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 1 1150 11501092	3^	GENRL	Injection site pain/ Pain at injection site	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Injection site pain/ arm soreness (L arm, injection site)	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1150 11501094	3^	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		RESP	Oropharyngeal pain/ Sore Throat	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	04SEP2020	2/4	2	Yes		NA	R (07SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11150 11501098	3^	GENRL	Injection site pain/ Pain at injection Site	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	03SEP2020	1/3	3	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	04SEP2020	2/2	3	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 11150 11501100	3^	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/4	3	Yes		NA	R (27SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	03SEP2020	1/3	2	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ Chills	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
			Pain/ Body Aches	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
	Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N		
	NERV	Headache/ Headache	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11150 11501101	3^	MUSC	Pain in extremity/ arm soreness (L arm)	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		PSYCH	Insomnia/ Trouble Sleeping	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 11150 11501104	3^	GENRL	Injection site pain/ left injection site arm soreness	1	09SEP2020	2/1	3	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 11150 11501106	3^	GENRL	Injection site pain/ Arm soreness (Left arm/injection site)	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 11150 11501110	3^	GENRL	Fatigue/ Fatigue	2	03OCT2020	3/2	1	Yes		NA	R (04OCT2020)	N/N
			Pain/ Body Aches	2	03OCT2020	3/2	1	Yes		NA	R (04OCT2020)	N/N
		NERV	Sciatica/ Sciatica Nerve Pain	2	08OCT2020	8/C	1	No	O	NA	RG	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	1	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1150 11501111		NERV	Dizziness/ Lightheaded	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1150 11501113	3^	MUSC	Pain in extremity/ Arm Pain (Left arm)	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1150 11501114	3^	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Pain in extremity/ Arm Soreness (Left arm)	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1150 11501115	3^	GENRL	Fatigue/ Fatigue	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Injection site pain/ Injection site pain	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
			Pyrexia/ Fever (101.0)	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11150 11501117	3^	GENRL	Fatigue/ Fatigue	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 11152 11521010	3^	NERV	Headache/ headache, intermittent	1	13AUG2020	2/21	2	No	O	NA/TC	R (02SEP2020)	N/N
16-55/ C459100 11152 11521012	3^	INJ&P	Procedural pain/ post-surgical pain left shoulder	2	21SEP2020	20/22	2	No	O	NA/TC	R (12OCT2020)	N/N
16-55/ C459100 11152 11521046	3^	SKIN	Rash/ body rash	2	03SEP2020	3/C	2	Yes		NA/TC	N	N/N
16-55/ C459100 11152 11521077	3^	GASTR	Toothache/ tooth pain	1	27AUG2020	15/1	2	No	O	NA/TC/TCN	R (27AUG2020)	N/N
16-55/ C459100 11152 11521085	3^	GENRL	Unevaluable event/ Unknown of Unknown Origin	1	26AUG2020	8/1	4	No	O	P/W	F (26AUG2020)	Y/N
16-55/ C459100 11152 11521138	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	1	14SEP2020	25/7	1	No	O	NA/TC	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11152 11521147	3^	INJ&P	Contusion/ Antecubital bruise of the right arm	2	08OCT2020	29/15	1	No	O	NA	R (22OCT2020)	N/N
16-55/ C459100 11152 11521149	3^	PSYCH	Depression/ worsening depression	2	28SEP2020	18/18	2	No	O	NA/TC	R (15OCT2020)	N/N
16-55/ C459100 11152 11521165	3^	GASTR	Nausea/ nausea	2	22SEP2020	9/3	2	No	O	NA/TC	R (24SEP2020)	N/N
16-55/ C459100 11152 11521182	3^	GENRL	Injury associated with device/ needle stick injury (finger)	1	26AUG2020	3/1	1	No	O	NA/TC	R (26AUG2020)	N/N
16-55/ C459100 11152 11521183	3^	INFEC	Genital herpes/ genital herpes diagnosed	1	04SEP2020	12/7	2	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C459100 11152 11521209	3^	RESP	Throat irritation/ irritated throat	1	02SEP2020	8/6	1	No	O	NA	R (07SEP2020)	N/N
16-55/ C459100 11152 11521227	3^	GENRL	Injury associated with device/ needle stick injury, right foot	2	27SEP2020	11/1	2	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C459100	3^	NERV	Neuropathy peripheral/ neuropathy	1	05SEP2020	6/6	2	No	O	NA/TC	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11152 11521276	3^	GENRL	Injection site pain/ injection site pain	1	04SEP2020	2/4	3	Yes		NA/TC	R (07SEP2020)	N/N
11152 11521308		GENRL	Fatigue/ fatigue	1	08SEP2020	6/5	2	No	O	NA	R (12SEP2020)	N/N
		MUSC	Myalgia/ myalgia	1	08SEP2020	6/4	2	No	O	NA	R (11SEP2020)	N/N
16-55/ C459100 11152 11521318	3^	PSYCH	Insomnia/ worsening insomnia	1	03SEP2020	1/8	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 11152 11521365	3^	SKIN	Pruritus/ itchy scalp	2	05OCT2020	8/25	2	Yes		NA/TC/TCN	R (29OCT2020)	N/N
			Rash/ rash back of neck	2	05OCT2020	8/25	2	Yes		NA/TC	R (29OCT2020)	N/N
			Rash/ rash bilateral arms	2	05OCT2020	8/25	2	Yes		NA/TC	R (29OCT2020)	N/N
16-55/ C459100 11152 11521436	3^	GASTR	Proctalgia/ Rectal Pain	2	03NOV2020	36/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100	3^	INJ&P	Limb injury/ injured right arm	1	27SEP2020	19/4	1	No	O	NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1152 11521437	3^	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	1/1	2	No	O	NA	R (16SEP2020)	N/N
1 1152 11521449		GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	1/1	2	No	O	NA	R (09OCT2020)	N/N
16-55/ C459100	3^	GASTR	Diarrhoea/ diarrhea	2	16OCT2020	5/6	3	Yes		NA	R (21OCT2020)	N/N
1 1152 11521467	3^	CARD	Palpitations/ Heart Palpitations	1	11OCT2020	18/C	2	No	O	NA	RG	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/N
1 1152 11521474			Injection site pain/ INJECTION-SITE SORENESS	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C459100		GASTR	Diarrhoea/ DIARRHEA	1	24AUG2020	6/1	1	Yes		NA	R (24AUG2020)	N/N
1 1156 11561002		GENRL	Pyrexia/ FEVER	1	24AUG2020	6/1	1	Yes		NA	R (24AUG2020)	N/N
		RESP	Cough/ COUGH	1	24AUG2020	6/1	1	No	O	NA	R (24AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11156 11561006	3^	RESP	Pulmonary embolism/ PULMONARY EMBOLISM	1	31AUG2020	12/3	3	No	O	NA/TC	R (02SEP2020)	N/N
		VASC	Deep vein thrombosis/ DEEP VEIN THROMBOSIS	1	31AUG2020	12/10	3	No	O	NA/TC	R (09SEP2020)	Y/N
		MUSC	Musculoskeletal stiffness/ right shoulder stiffness	1	05SEP2020	17/3	1	No	O	NA/TCN	R (07SEP2020)	N/N
16-55/ C459100 11156 11561007	3^	PREG	Abortion spontaneous incomplete/ INCOMPLETE SPONTANEOUS ABORTION	2	04OCT2020	25/4	3	No	O	NA/TCN	R (07OCT2020)	Y/N
		RESP	Haemoptysis/ HEMOPTYSIS	2	04OCT2020	25/1	2	No	O	NA	R (04OCT2020)	N/N
16-55/ C459100 11156 11561008	3^	GENRL	Chills/ Chills	1	27AUG2020	8/2	1	Yes		NA	R (28AUG2020)	N/N
		MUSC	Myalgia/ muscle aches	1	27AUG2020	8/2	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 11156 11561009	3^	GENRL	Injection site pain/ Injection Site Pain (left deltoid)	1	03SEP2020	15/6	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C459100 11156 11561015	3^	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY*		21AUG2020	1/C		No	O	P	UNK	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11156 11561018	3^	REPRO	Dysfunctional uterine bleeding/ DYSFUNCTIONAL UTERINE BLEEDING	1	10SEP2020	18/22	2	No	O	NA/TC	R (01OCT2020)	N/N
		INFEC	Urinary tract infection/ ACUTE URINARY TRACT INFECTION	2	30SEP2020	16/7	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100 11156 11561048	3^	GENRL	Pyrexia/ fever	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		MUSC	Arthralgia/ arthralgia	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 11156 11561054	3^	RESP	Dyspnoea/ Shortness of breath	1	04SEP2020	8/2	1	No	O	NA	R (05SEP2020)	N/N
		MUSC	Arthralgia/ arthralgia	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 11156 11561057	3^	GENRL	Pyrexia/ fever	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		MUSC	Arthralgia/ arthralgia	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 11156 11561076	3^	RESP	Oropharyngeal pain/ sore throat	1	03SEP2020	3/2	1	Yes		NA/TCN	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1156 11561089	3^	GENRL	Pyrexia/ fever	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		MUSC	Myalgia/ myalgia	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1156 11561090	3^	GENRL	Injection site pain/ Injection Site Pain (Left Shoulder)	1	04SEP2020	2/5	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C459100 1 1156 11561111	3^	MUSC	Back pain/ Back Pain	2	08OCT2020	7/6	1	No	O	NA/TCN	R (13OCT2020)	N/N
		RENAL	Urethral discharge/ Urethral Discharge	2	08OCT2020	7/10	1	No	O	NA/TC	R (17OCT2020)	N/N
		INFEC	Otitis externa/ external otitis	1	11SEP2020	4/6	1	No	O	NA/TC	R (16SEP2020)	N/N
		REPRO	Vaginal discharge/ Vaginal discharge	2	29SEP2020	2/22	1	No	O	NA/TC	R (20OCT2020)	N/N
		INFEC	Vaginal infection/ ACUTE VAGINITIS	2	20OCT2020	23/7	1	No	O	NA/TC	R (26OCT2020)	N/N
		METAB	Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2	20OCT2020	23/C	1	No	O	NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11156 11561121	3^	GASTR	Diarrhoea/ diarrhea	1	10SEP2020	2/9	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Arthralgia/ left shoulder pain	1	10SEP2020	2/5	1	Yes		NA	R (14SEP2020)	N/N
		RESP	Oropharyngeal pain/ sore throat	1	10SEP2020	2/5	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C459100 11156 11561159	3^	GASTR	Diarrhoea/ diarrhea	1	27SEP2020	7/2	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C459100 11156 11561166	3^	SKIN	Dermal cyst/ sebaceous cyst	1	06OCT2020	14/C	1	No	O	NA	RG	N/N
		GASTR	Vomiting/ VOMITING	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 11156 11561172	3^	GASTR	Gastritis/ GASTRITIS	1	28SEP2020	4/C	1	No	O	NA/TC	RG	N/N
		NEOPL	Acrochordon/ ACROCHORDON	1	28SEP2020	4/C	1	No	O	NA	RG	N/N
16-55/ C459100 11157 11571113	3^	MUSC	Myalgia/ Myalgia	1	02SEP2020	2/6	1	Yes		NA	R (07SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11157 11571114	3^	GENRL	Chills/ Chills	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
		GASTR	Nausea/ Nausea	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 11157 11571115	3^	GENRL	Pain/ Body Aches	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 11157 11571125	3^	GENRL	Injection site pain/ Pain at the injection site	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 11157 11571126	3^	MUSC	Myalgia/ General Muscle Aches	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		IMMUN	Allergy to arthropod bite/ Allergic reaction to mosquito bite	2	01OCT2020	9/10	2	No	O	NA/TC	R (10OCT2020)	N/N
		NERV	Headache/ Headache	1	16SEP2020	16/5	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C459100 11157 11571132	3^	GENRL	Injection site erythema/ Redness at injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 11157 11571141	3^	GENRL	Injection site swelling/ Swelling at injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
			INFECC	Sinusitis/ Sinusitis	2	03OCT2020	12/13	2	No	O	NA/TC	R (15OCT2020)	N/N
			GENRL	Injection site erythema/ Redness at injection site	2	27OCT2020	1/8	1	Yes		NA	R (03NOV2020)	N/N
			GENRL	Injection site induration/ Induration at injection site	2	27OCT2020	1/8	1	Yes		NA	R (03NOV2020)	N/N
			GENRL	Chills/ Chills	2	28OCT2020	2/5	1	Yes		NA/TC	R (01NOV2020)	N/N
			MUSC	Myalgia/ Myalgia	2	28OCT2020	2/5	1	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C459100 11161 11611011	3^	EAR	Headache/ Headache	2	28OCT2020	2/5	1	Yes		NA/TC	R (01NOV2020)	N/N	
			Excessive cerumen production/ Excess cerumen, It EAC	1	16OCT2020	77/C	1	No	O	NA	N	N/N	
16-55/ C459100 11161 11611020	3^	BLOOD	Lymphadenopathy/ 1+right distal cervical lymph node enlarged	1	08NOV2020	98/C	1	No	O	NA	N	N/N	
16-55/ C459100 11162 11621019	3^	INFECC	Sinusitis/ sinus infection	2	06OCT2020	42/C	1	No	O	NA/TC	N	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11162 11621025	3^	GASTR	Gastroesophageal reflux disease/ Esophageal pain/Acid Reflux	1	13AUG2020	10/2	1	No	O	NA	R (14AUG2020)	N/N
16-55/ C459100 11162 11621103	3^	NERV	Headache/ Headache	2	05SEP2020	2/3	1	No	O	NA	R (07SEP2020)	N/N
16-55/ C459100 11162 11621121	3^	RESP	Nasal congestion/ Nasal Congestion	2	02OCT2020	31/2	1	No	O	NA	R (03OCT2020)	N/N
16-55/ C459100 11162 11621128	3^	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	SEP2020	1/C		No	O	NA	UNK	N/N
16-55/ C459100 11162 11621137	3^	NERV	Tension headache/ Stress induced Headache	2	14SEP2020	6/2	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C459100 11162 11621142	3^	GENRL	Pyrexia/ Fever	1	20AUG2020	4/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C459100 11162 11621151	3^	NERV	Headache/ Headache	2	14OCT2020	35/1	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11162 11621158			Injection site pain/ Left shoulder soreness (injection site pain)	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Pyrexia/ Slight increased fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		EAR	Vertigo/ Intermittent Vertigo	2	27SEP2020	19/26	1	No	O	NA	R (22OCT2020)	N/N
16-55/ C459100 11162 11621166	3^	GASTR	Diarrhoea/ Diarrhea	2	11OCT2020	26/2	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C459100 11162 11621205	3^	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
		NERV	Headache/ Headache	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 11162 11621279	3^	NERV	Migraine/ Migraine	2	12OCT2020	19/17	1	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C459100 11162 11621283	3^	INFEC	Pharyngitis streptococcal/ Strep Throat	2	12OCT2020	18/11	1	No	O	NA/TC/TCN	R (22OCT2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	14SEP2020	5/2	1	No	O	NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11162 11621324		RESP	Oropharyngeal pain/ Sore throat	1	14SEP2020	5/2	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C459100 11162 11621392	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/Y
16-55/ C459100 11162 11621392		RESP	Oropharyngeal pain/ Sore throat	1	18SEP2020	2/2	1	No	O	NA	R (19SEP2020)	N/N
16-55/ C459100 11162 11621416	3^	GENRL	Chills/ Chills	1	02OCT2020	12/1	1	No	O	NA	R (02OCT2020)	N/N
16-55/ C459100 11162 11621464	3^	NERV	Hypoaesthesia/ Leg Numbness	1	05OCT2020	6/2	1	No	O	NA	R (06OCT2020)	N/N
		NERV	Nerve compression/ Pinched Nerve	2	OCT2020	1/C	1	No	O	NA	R	N/N
16-55/ C459100 11163 11631040	3^	INFEC	Urinary tract infection/ UTI	1	22AUG2020	17/7	2	No	O	NA/TC	R (28AUG2020)	N/N
16-55/ C459100 11163 11631059	3^	UNC	UPPER BODYRASH DUE TO VACCINE@@/ UPPER BODYRASH DUE TO VACCINE	1	08AUG2020	2/18	2	Yes		P/TC	R (25AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11163 11631069	3^	PSYCH	Depression/ DEPRESSION	1	01SEP2020	23/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 11163 11631077	3^	GENRL	Pyrexia/ FEVER	2	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 11166 11661003	3^	GENRL	Injection site pain/ Injection site soreness	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
			Pyrexia/ Low grade fever	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 11166 11661030	3^	VASC	Hot flush/ Exacerbation of hot flashes	2	02OCT2020	22/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 11166 11661036	3^	NERV	Dysgeusia/ Metallic taste	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		PSYCH	Insomnia/ Insomnia	1	21AUG2020	2/9	2	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 11166 11661046	3^	GENRL	Pyrexia/ Fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11166 11661047	3^	NERV	Dizziness/ Dizziness	1	31AUG2020	1/1	1	Yes		P	R (31AUG2020)	N/N
16-55/ C459100 11166 11661063	3^	GENRL	Pyrexia/ Fever	2	25SEP2020	1/31	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 11166 11661076	3^	INJ&P	Contusion/ LEFT UPPER CHEST BRUISING.	1	25SEP2020	11/C	1	No	O	NA/TC	N	N/N
			Road traffic accident/ Motor vehicle accident (MVA)	1	25SEP2020	11/1	1	No	O	NA	R (25SEP2020)	N/N
			Skin abrasion/ SUPERFICIAL ABRAISIONS, dorsal wrist, right.	1	25SEP2020	11/C	1	No	O	NA	N	N/N
			Skin abrasion/ SUPERFICIAL ABRAISIONS, dorsal wrists, left	1	25SEP2020	11/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 11166 11661087	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/1	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 11167 11671009	3^	HEPAT	Cholecystitis acute/ Acute Cholecystitis	1	21AUG2020	5/2	3	No	O	NA/TC/TCN	R (22AUG2020)	Y/N
			Cholelithiasis/ Cholelithiasis	1	21AUG2020	5/2	2	No	O	NA/TCN	RS (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11167 11671021	3^	INJ&P	Muscle strain/ Back Strain	2	14OCT2020	36/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 11167 11671120	3^	INFEC	Cellulitis/ Cellulitis nose	2	27SEP2020	6/21	2	No	O	NA/TC	R (17OCT2020)	N/N
16-55/ C459100 11167 11671130	3^	METAB	Type 2 diabetes mellitus/ Worsening Type 2 diabetes	1	09SEP2020	7/C	2	No	O	NA/TC	N	N/N
		VASC	Hypertension/ Hypertension with microalbumin	1	09SEP2020	7/C	1	No	O	NA/TC	N	N/N
		GASTR	Nausea/ Nausea	1	22SEP2020	20/1	1	No	CD	NA	R (22SEP2020)	N/N
		GENRL	Chest pain/ Chest pain	1	22SEP2020	20/1	2	No	CD	NA	R (22SEP2020)	N/N
16-55/ C459100 11167 11671175	3^	NERV	Cerebrovascular accident/ Cerebrovascular accident	2	21OCT2020	23/C	3	No	O	NA/TC	RG	Y/N
16-55/ C459100 11168 11681016	3^	GASTR	Nausea/ nausea, not COVID related	1	15AUG2020	3/1	1	No	O	NA	R (15AUG2020)	N/N
16-55/ C459100 11168 11681024	3^	SKIN	Urticaria/ HIVES(NECK)	2	22SEP2020	19/5	1	No	CD	NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11168 11681054	3^	GENRL	Chills/ chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		SKIN	Cold sweat/ cold sweat	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 11168 11681073	3^	SKIN	Rash/ upper body rash	2	13SEP2020	3/2	1	Yes		NA/TC	R (14SEP2020)	N/N
		SKIN	Rash/ intermittent upper body rash	2	18SEP2020	8/25	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C459100 11168 11681109	3^	MUSC	Pain in extremity/ Intermittent pain in both feet	1	06SEP2020	10/6	1	No	O	NA	R (11SEP2020)	N/N
		GENRL	Peripheral swelling/ Intermittent Swelling in the L hand	1	09SEP2020	13/3	1	No	O	NA	R (11SEP2020)	N/N
16-55/ C459100 11168 11681132	3^	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ Injection site pain	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 11168 11681138	3^	GASTR	Nausea/ nausea	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11168 11681162	3^	GENRL	Pyrexia/ low grade fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		MUSC	Back pain/ low back pain	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ headache	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Chills/ chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		GENRL	Pyrexia/ low grade fever	2	14OCT2020	2/3	1	Yes		NA/TC	R (16OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	14OCT2020	2/6	1	Yes		NA/TC	R (19OCT2020)	N/N
16-55/ C459100 11168 11681198	3^	INFEC	Sinusitis/ SINUS INFECTION	1	27SEP2020	5/8	1	No	O	NA/TC	R (04OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11168 11681210	3^	GENRL	Chills/ chills	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
			Pain/ body aches	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
			Pyrexia/ fever	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Chills/ chills	2	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N
			Pain/ body aches	2	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N
			Pyrexia/ fever	2	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 11168 11681213	3^	GENRL	Fatigue/ fatigue	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 11168 11681215	3^	GENRL	Injection site pain/ injection site soreness	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Fatigue/ fatigue	1	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11169 11691001	3^	MUSC	Myalgia/ muscle ache	1	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Injection site pain/ Pain at Injection Site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/Y
		NERV	Headache/ Headache	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/Y
		GENRL	Injection site induration/ Red induration at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
			Injection site pain/ Soreness at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 11169 11691002	3^		Injection site warmth/ Warmth at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Malaise/ General Malaise	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 11169 11691007	3^	RESP	Oropharyngeal pain/ Sore Throat	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100	3^	BLOOD	Lymphadenopathy/ Swollen Right Axillary lymph node	1	03SEP2020	1/40	1	Yes		NA	R (12OCT2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1169 11691010		GENRL	Injection site pain/ Injection Site pain	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/Y
16-55/ C459100 1 1169 11691011	3^	MUSC	Arthralgia/ Painful Left Knee	1	08SEP2020	6/4	1	No	O	NA/TC	R (11SEP2020)	N/N
			Joint swelling/ swelling Left knee	1	08SEP2020	6/4	1	No	O	NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at injection site	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	12OCT2020	21/3	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C459100 1 1169 11691012	3^	GENRL	Injection site pain/ Arm pain at Injection Site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Sensation of foreign body/ Globus Sensation of the throat	1	06SEP2020	3/19	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ Arm pain at Injection Site	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1169 11691017	3^	GENRL	Injection site pain/ Mild Soreness at Injection Site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100	3^	MUSC	Pain in extremity/ Left Arm pain	2	30SEP2020	1/2	2	Yes		NA/TCN	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11169 11691019		GENRL	Chills/ Chills	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11169 11691020	3^	GENRL	Injection site pain/ Tenderness at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
			Injection site swelling/ Swelling at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
			Injection site pain/ Soreness at Injection Site	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
		NERV	Mental impairment/ Mental Fogginess	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	03OCT2020	3/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 11169 11691023	3^	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Moderate Pain at Injection Site	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
			Injection site swelling/ Mild swelling at Injection site	2	29SEP2020	1/3	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	1	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1169 11691024			Injection site swelling/ 2 cm swelling at injection site	1	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
			Injection site erythema/ Redness at Injection Site	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
			Injection site pain/ Moderate pain at injection Site	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
			Injection site swelling/ Swelling at Injection Site	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1169 11691026	3^	GASTR	Diarrhoea/ Diarrhea	1	13SEP2020	5/2	1	No	O	NA	R (14SEP2020)	N/N
16-55/ C459100 1 1169 11691029	3^	GENRL	Fatigue/ Fatigue	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
			Injection site pain/ Pain at Injection Site	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
			Injection site pain/ Tenderness at Injection Site	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11169 11691030	3^	MUSC	Injection site pain/ Pain at Injection Site	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
			Injection site pain/ Tenderness at Injection site	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
			Myalgia/ Muscle Aches	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 11169 11691031	3^	GENRL	Pain in extremity/ pain in left arm	1	10SEP2020	1/4	1	Yes		NA/TC	R (13SEP2020)	N/N
			Injection site pain/ Moderate Pain at Injection Site	2	01OCT2020	1/4	2	Yes		NA/TC	R (04OCT2020)	N/N
			Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 11169 11691033	3^	NERV	Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ Mild pain at Injection Site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Headache/ Headache	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Injection site bruising/ Bruise at Injection Site	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
			Injection site pain/ Soreness at Injection Site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11169 11691036	3^	GENRL	Injection site pain/ Tenderness at injection site	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at Injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 11169 11691040	3^	GASTR	Nausea/ Nausea	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
		GENRL	Pain/ Body Aches	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
		MUSC	Arthralgia/ Joint Aches	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C459100 11169 11691041	3^	GENRL	Injection site pain/ Injection Site Soreness	1	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N
		GENRL	Malaise/ General malaise	1	12SEP2020	2/3	1	Yes		NA/TC	R (14SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	03OCT2020	2/3	1	Yes		NA/TC	R (05OCT2020)	N/N
		GENRL	Injection site pain/ injection site soreness	2	03OCT2020	2/3	1	Yes		NA/TC	R (05OCT2020)	N/N
16-55/ C459100	3^	GENRL	Malaise/ malaise	2	03OCT2020	2/3	1	Yes		NA/TC	R (05OCT2020)	N/N
		GENRL	Chills/ Chills	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1169 11691043			Pyrexia/ Fever of 100.7	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1169 11691047	3^	GENRL	Injection site pain/ Pain at injection site	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ Tenderness at injection site	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ Pain at Injection Site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1169 11691049	3^	GENRL	Injection site pain/ Painful Right Arm Injection Site	1	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ Fever	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ Headache	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
			Injection site pain/ Injection Site Pain	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1169 11691056	3^	GENRL	Pyrexia/ Fever	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
			Injection site pain/ Pain at injection Site	2	08OCT2020	1/4	2	Yes		NA/TC	R (11OCT2020)	N/N
			Pyrexia/ Fever of 99.9	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1169 11691057	3^	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
			Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
			Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1169 11691059	3^	MUSC	Pain/ Generalized Body Aches	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
			Pyrexia/ Fever	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
			Pain in extremity/ Left Arm Pain	1	18SEP2020	2/6	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1169 11691062	3^	GASTR	Nausea/ Nausea	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 11169 11691065	3^	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
			Pain/ Generalized Body Aches	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
		MUSC	Pain in extremity/ Sore Left Arm	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
		3^	GENRL	Injection site pain/ injection site pain	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
			MUSC	Joint range of motion decreased/ mild range of motion deficit left arm	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
			GENRL	Injection site pain/ mild pain at injection site	2	09OCT2020	1/3	1	Yes		NA/TC/TCN	R (11OCT2020)	N/N
			MUSC	Joint range of motion decreased/ Limited range of motion in left arm	2	09OCT2020	1/3	1	Yes		NA/TC/TCN	R (11OCT2020)	N/N
16-55/ C459100 11169 11691067	3^	GENRL	Injection site pain/ Pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
			INFEC	Urinary tract infection/ Urinary Tract Infection	2	15OCT2020	7/13	2	No	O	NA/TC	R (27OCT2020)	N/N
			SKIN	Pruritus/ Pruritis	2	29OCT2020	21/C	2	No	O	NA/TC	RG	N/N
			Urticaria/ Hives- Entire Body	2	29OCT2020	21/C	2	No	O	NA/TC	RG	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11169 11691072	3 [^]	GENRL	Injection site pain/ Pain at injection site	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ Tenderness at injection site	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Chills/ Chills	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 11169 11691073	3 ^{^†}	GASTR	Diarrhoea/ Diarrhea	1	08OCT2020	8/1	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C459100 11170 11701003	3 [^]	GENRL	Fatigue/ Fatigue	2	26SEP2020	27/2	1	Yes		NA	R (27SEP2020)	N/N
			Pain/ Body Aches	2	26SEP2020	27/2	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ Headache	2	26SEP2020	27/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 11170 11701020	3 [^]	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/4	1	Yes		NA	R (21AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1170 11701021	3^	MUSC	Arthralgia/ Joint Pain	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Pain at Injection Site	1	18AUG2020	2/5	1	Yes		NA	R (22AUG2020)	N/N
		NERV	Headache/ Headache	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C459100 1 1170 11701022	3^	GENRL	Injection site swelling/ Injection Site Swelling	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Pain/ Exercise Induced Body Soreness	1	06SEP2020	21/2	1	No	O	NA/TC	R (07SEP2020)	N/N
		NERV	Headache/ Headache	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1170 11701023	3^	GASTR	Nausea/ Nausea	2	05SEP2020	2/2	1	Yes		NA/TC	R (06SEP2020)	N/N
		GENRL	Chills/ Chills	2	05SEP2020	2/2	1	Yes		NA/TC	R (06SEP2020)	N/N
		GENRL	Malaise/ Malaise	2	05SEP2020	2/2	1	Yes		NA/TC	R (06SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	05SEP2020	2/2	1	Yes		NA/TC	R (06SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	05SEP2020	2/2	1	Yes		NA/TC	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701029	3^	GENRL	Injection site erythema/ Injection Site Redness	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
			Injection site pain/ Injection Site Pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
		NERV	Headache/ Headache	1	18AUG2020	1/2	1	Yes		NA/TC	R (19AUG2020)	N/N
		GENRL	Pyrexia/ Fever	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
			Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Chest pain/ Chest Pain	2	10SEP2020	2/2	1	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C459100 11170 11701034	3^	GENRL	Fatigue/ Fatigue	2	12SEP2020	4/2	1	Yes		NA	R (13SEP2020)	N/N
			Pyrexia/ Fever	2	12SEP2020	4/2	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	12SEP2020	4/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1170 11701036	3^	GENRL	Injection site pain/ Pain at Injection Site	2	09SEP2020	1/4	1	Yes		NA/TC	R (12SEP2020)	N/N
1170 11701038		GENRL	Fatigue/ Fatigue	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1170 11701043	3^	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		NERV	Headache/ Headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1170 11701044	3^	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		SKIN	Rash pruritic/ Itchy Pink Rash (bilateral forearms, upper back, top of head at forehead and scalp)	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701047	3^	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
			Pyrexia/ Fever	2	12SEP2020	2/2	2	Yes		NA/TC	R (13SEP2020)	N/N
			MUSC Myalgia/ Myalgias	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
			NERV Headache/ Headache	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100 11170 11701049	3^	GENRL	Chills/ Chills	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
			Fatigue/ Fatigue	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ Fever	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
			MUSC Myalgia/ Generalized Muscle Pain	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
			NERV Headache/ Headache	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 11170 11701055	3^	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ Injection Site Pain	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1170 11701057	3^	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/3	2	Yes		NA/TC	R (23AUG2020)	N/N
			Pyrexia/ Fever	1	21AUG2020	1/2	2	Yes		NA	R (22AUG2020)	N/N
16-55/ C459100 1 1170 11701063	3^	GENRL	Injection site pain/ Pain at Injection Site	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1170 11701065	3^	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		MUSC	Arthralgia/ Joint Pain	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
			Myalgia/ Myalgias	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1170 11701069	3^	GENRL	Chills/ Chills	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1170 11701073	3^	GENRL	Fatigue/ Fatigue	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
			Injection site pain/ Injection Site Pain	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
			Pyrexia/ Fever	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
			MUSC Myalgia/ Muscle Pain	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
			GENRL Injection site pain/ Injection Site Pain	1	26AUG2020	2/4	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 1 1170 11701075	3^	GENRL	GENRL Injection site pain/ Injection Site Pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
			Fatigue/ Fatigue	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
			NERV Injection site pain/ Injection Site Soreness	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
			NERV Pyrexia/ Fever	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
			NERV Headache/ Headache	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1170 11701079	3^	GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1170 11701085	3^	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N	
			Injection site pain/ Injection Site Pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N	
		MUSC	Myalgia/ Muscle Pain	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N	
		GENRL	Fatigue/ Fatigue	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N	
		GENRL	Injection site pain/ Injection Site Pain	1	26AUG2020	1/3	2	Yes		NA	R (28AUG2020)	N/N	
			Fatigue/ Fatigue	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N	
			Injection site pain/ Pain at Injection Site	2	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N	
			Pyrexia/ Fever	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N	
			MUSC	Myalgia/ Muscle Pain	2	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
			NERV	Headache/ Headache	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1170 11701087	3^	GENRL	Injection site erythema/ Injection Site Redness	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	
			Injection site pain/ Injection Site Pain	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701089	3^	GENRL	Pyrexia/ Fever	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 11170 11701091	3^	GENRL	Chills/ Chills	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Injection site erythema/ Injection Site Redness	2	17SEP2020	2/8	1	Yes		NA	R (24SEP2020)	N/N
			Injection site swelling/ Injection Site Swelling	2	17SEP2020	2/8	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ Muscle Pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 11170 11701093	3^	GENRL	Injection site pain/ Pain at Injection Site	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N
			Injection site swelling/ Swelling at Injection Site	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1170 11701094	3^	GENRL	Injection site pain/ Pain at Injection Site	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
			Injection site swelling/ Injection Site Swelling	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
			MUSC Myalgia/ Generalized Muscle Pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
			NERV Headache/ Headache	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
			Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1170 11701096	3^	MUSC	Injection site pain/ Pain at Injection Site	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Myalgia/ Myalgias	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
			NERV Headache/ Headache	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
			GENRL Pyrexia/ Fever	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 1 1170 11701099	3^	GENRL	Injection site pain/ Pain at injection site	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1170 11701102		NERV	Headache/ Headache	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1170 11701103	3^	GASTR	Nausea/ Nausea	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		GENRL	Chills/ Chills	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
			Malaise/ Malaise	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
			Pyrexia/ Fever	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
		NERV	Headache/ Headache	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1170 11701105	3^	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701106	3^	NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ Pain at Injection Site	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ Fever	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Arthralgia/ Joint Pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Myalgia/ Generalized Muscle Pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 11170 11701111	3^	NERV	Headache/ Headache	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	27AUG2020	1/3	2	Yes		NA	R (29AUG2020)	N/N
		GENRL	Pyrexia/ Fever	1	28AUG2020	2/2	2	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 11170 11701112	3^	GENRL	Injection site pain/ Injection Site Pain	2	18SEP2020	1/2	2	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701116	3^	IMMUN	Drug hypersensitivity/ Allergic Reaction to Lisinopril	1	15SEP2020	19/2	3	No	O	NA/TC	R (16SEP2020)	N/N
		GENRL	Injection site swelling/ Injection Site Swelling	2	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 11170 11701120	3^	MUSC	Myalgia/ Muscle Pain Generalized	1	28AUG2020	1/2	1	Yes		NA/TC	R (29AUG2020)	N/N
		GENRL	Injection site pain/ Pain at Injection Site	1	28AUG2020	1/2	2	Yes		NA/TC	R (29AUG2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Pain	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 11170 11701121	3^	GENRL	Injection site erythema/ Injection Site Redness	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Injection site swelling/ Injection Site Swelling	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		MUSC	Myalgia/ Muscle Pain	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701122	3^	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
		NERV	Headache/ Headache	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
		GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ Injection Pain Site	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Pyrexia/ Fever	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ Muscle Pain	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	
16-55/ C459100 11170 11701123	3^	GASTR	Nausea/ Nausea	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Chills/ Chills	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Fatigue/ Fatigue	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		METAB	Decreased appetite/ Poor Appetite	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1170 11701126	3^	MUSC	Myalgia/ Myalgias	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Chills/ Chills	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N
			Injection site pain/ Injection Site Pain	1	28AUG2020	1/8	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Chills/ Chills	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
			Fatigue/ Fatigue	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1170 11701128	3^	GENRL	Injection site pain/ Injection Site Pain	2	17SEP2020	1/8	1	Yes		NA	R (24SEP2020)	N/N
			Fatigue/ Fatigue	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1170 11701129	3^		Pyrexia/ Fever	2	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Injection site pain/ Injection Pain Site	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701131	3^	GENRL	Chills/ Chills	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
			Injection site pain/ Injection Site Pain	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Chills/ Chills	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 11170 11701138	3^	GENRL	Fatigue/ Fatigue	1	31AUG2020	1/3	2	Yes		NA	R (02SEP2020)	N/N
			Injection site erythema/ Injection Site Redness	1	31AUG2020	1/8	1	Yes		NA	R (07SEP2020)	N/N
		MUSC	Injection site pain/ Injection Site Pain	1	31AUG2020	1/4	2	Yes		NA/TC	R (03SEP2020)	N/N
			Myalgia/ Generalized Muscle Pain	1	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N
			NERV	Headache/ Headache	1	02SEP2020	3/6	2	Yes		NA	R (07SEP2020)
		GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
			Fatigue/ Fatigue	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1170 11701143	3^	MUSC	Myalgia/ Generalized Muscle Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ Headache	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
			Injection site pain/ Injection Site Pain	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
		NERV	Headache/ Headache	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N
		GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Injection site erythema/ Injection Site Redness	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1170 11701144	3^		Injection site pain/ Injection Site Pain	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		GASTR	Gingival pain/ Gum Tingling Pain	1	04SEP2020	5/1	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701145	3^	GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ Muscle Pain	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		INFEC	Sinusitis/ Sinus Infection	2	02OCT2020	12/8	2	No	O	NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N	
	GENRL	Pain/ Body Aches	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N	
	GENRL	Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
	MUSC	Pain in extremity/ Arm Pain	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N	
	3^	GENRL	Injection site pain/ Pain at injection site	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
3^	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ Chills	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
			Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 11170 11701153	3^	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 11170 11701156	3^	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 11170 11701158	3^	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C459100 11170 11701159	3^	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701163	3^	EYE	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
			Blepharitis/ Blepharitis of the left eye	1	15SEP2020	15/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 11170 11701165	3^	GENRL	Chills/ Chills	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 11170 11701166	3^	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	24SEP2020	1/5	1	Yes		NA	R (28SEP2020)	N/N
			Arthralgia/ Joint Pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Myalgia/ Muscle Pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 11170 11701167	3^	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 11170 11701167	3^	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 11170 11701174	3^	GENRL	Chills/ Chills	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	
			Fatigue/ Fatigue	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	
			Pyrexia/ Fever	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N	
		MUSC		Myalgia/ Generalized Muscle Pain	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL		Injection site pain/ Injection Site Pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Chills/ Chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
			Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
			Pyrexia/ Fever	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N	
		MUSC		Myalgia/ Generalized Muscle Pain	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL		Fatigue/ Fatigue	1	03SEP2020	2/4	1	Yes		NA/TC	R (06SEP2020)	N/N
				Injection site pain/ Injection Site Pain	1	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N
				Injection site pain/ Injection Site Soreness	1	03SEP2020	2/4	2	Yes		NA/TC	R (06SEP2020)	N/N
MUSC		Arthralgia/ General Joint Pain	1	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701178	3^	NERV	Myalgia/ Myalgias	1	03SEP2020	2/4	1	Yes		NA/TC	R (06SEP2020)	N/N
			Headache/ Headache	1	03SEP2020	2/4	1	Yes		NA/TC	R (06SEP2020)	N/N
			Fatigue/ Fatigue	2	24SEP2020	2/C	2	Yes		NA/TC	RG	N/N
		MUSC	Injection site pain/ Injection Site Pain	2	24SEP2020	2/25	2	Yes		NA/TC	R (18OCT2020)	N/N
			Myalgia/ Myalgias	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
			Headache/ Headache	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
		EYE	Vision blurred/ Blurry Vision	2	30SEP2020	8/C	1	No	O	NA/TC	N	N/N
		NERV	Headache/ Headache	2	30SEP2020	8/C	1	No	O	NA/TC	N	N/N
		VASC	Hypertension/ High Blood Pressure	2	30SEP2020	8/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 11170 11701179	3^	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 11170 11701179	3^	GASTR	Diarrhoea/ Diarrhea	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701182	3^	GENRL	Fatigue/ Fatigue	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
			Injection site erythema/ Injection Site Redness	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
			Malaise/ Malaise	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		NERV	Headache/ Headache	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
			GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)
		GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
		NERV	Headache/ Headache	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
			GENRL	Fatigue/ Fatigue	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)
				Pyrexia/ Fever	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)
		MUSC	Myalgia/ General Muscle Pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
NERV	Headache/ Headache	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N		
	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N	
16-55/ C459100 11170 11701183	3^	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701187	3^	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
			Fatigue/ Fatigue	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
			Malaise/ Malaise	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 11170 11701190	3^	GENRL	Fatigue/ Fatigue	1	03SEP2020	1/2	2	Yes		NA	R (04SEP2020)	N/N
		NERV	Headache/ Headache	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 11170 11701192	3^	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 11170 11701193	3^	GENRL	Chills/ Chills	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
			Injection site pain/ Injection Site Pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Malaise/ Malaise	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1170 11701199	3^	GENRL	Fatigue/ Fatigue	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
			Injection site pain/ Injection Site Pain	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
		MUSC	Myalgia/ General Muscle Pain	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
		3^	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
			GASTR	Abdominal pain/ Abdominal Pain	1	18SEP2020	16/3	1	Yes		NA	R (20SEP2020)	N/N
			GENRL	Injection site pain/ Injection Site Pain	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			MUSC	Myalgia/ Generalized Muscle Pain	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		3^	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
			GENRL	Chills/ Chills	1	05SEP2020	3/1	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N	
		GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1170 11701206	3^	GENRL	Injection site erythema/ Injection site Redness	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
1 1170 11701207			Injection site pain/ Pain at injection Site	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1170 11701209	3^	GENRL	Injection site pain/ Injection Site Pain	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C459100 1 1170 11701210	3^	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C459100 1 1170 11701211	3^	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Injection site swelling/ Injection Site Swelling	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Pyrexia/ Fever	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/6	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1170 11701213		GENRL	Injection site pain/ Pain at Injection Site	2	29SEP2020	1/5	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1170 11701215	3^	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1170 11701221	3^	NERV	Headache/ Headache	2	01OCT2020	3/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1170 11701222	3^	NERV	Dysgeusia/ Metallic Taste	1	22SEP2020	15/8	1	No	O	NA	R (29SEP2020)	N/N
		NERV	Headache/ Headache	1	25SEP2020	18/1	1	No	O	NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1170 11701225	3^	GENRL	Pyrexia/ Fever	2	02OCT2020	4/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11170 11701226		NERV	Headache/ Headache	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 11170 11701227	3^	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Injection site swelling/ Injection Site Swelling	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Arthralgia/ Joint Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 11170 11701228	3^	GENRL	Injection site pain/ Injection Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Myalgia/ Muscle Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 11170 11701229	3^	GASTR	Diarrhoea/ Diarrhea	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701230	3^	GENRL	Chills/ Chills	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
			Fatigue/ Fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
			Injection site pain/ Injection Site Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11170 11701232	3^	GENRL	Chills/ Chills	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
			Fatigue/ Fatigue	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		MUSC	Myalgia/ Muscle Pain	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 11170 11701233	3^	NERV	Headache/ Headache	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 11170 11701234	3^	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701235	3^	NERV	Headache/ Headache	1	12SEP2020	4/8	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 11170 11701236	3^	GENRL	Injection site pain/ Pain at injection site	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11170 11701237	3^	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ Pain at Injection Site	2	30SEP2020	1/2	3	Yes		NA	R (01OCT2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11170 11701241	3^	NERV	Headache/ Headache	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 11170 11701244	3^	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Arthralgia/ Generalized Joint Pain	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701245	3^	GENRL	Myalgia/ Generalized Muscle Pain	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Chills/ Chills	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
			Fatigue/ Fatigue	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
			Injection site pain/ Pain at injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		NERV	Headache/ Headache	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Chills/ Chills	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N
		MUSC	Injection site erythema/ Redness at injection site	2	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N
		MUSC	Myalgia/ Muscle Pain	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 11170 11701252	3^	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701258	3^	GENRL	Injection site pain/ Pain at injection site	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 11170 11701261	3^	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		NERV	Headache/ Headache	1	11SEP2020	2/4	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ Headache	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 11170 11701263	3^	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 11170 11701268	3^	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Arthralgia/ Generalized Joint Pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
			Myalgia/ Generalized Muscle Pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1170 11701269	3 [^]	GENRL	Fatigue/ Fatigue	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Chills/ Chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ Pain at Injection Site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		MUSC	Arthralgia/ Joint Pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Myalgia/ Muscle Pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
			Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Chills/ Chills	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
			Injection site erythema/ Redness at Injection Site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	Injection site pain/ Injection Site Pain	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N		
	Pyrexia/ Fever	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N		
	NERV	Headache/ Headache	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701279	3^	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Pyrexia/ Fever	1	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100 11170 11701281	3^	GENRL	Injection site pain/ Injection Site Sore (Left Arm)	1	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	12SEP2020	3/4	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	12SEP2020	3/4	1	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	1	12SEP2020	3/4	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 11170 11701285	3^	GENRL	Injection site erythema/ Injection Site Redness	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
		NERV	Headache/ Headache	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701286	3^	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 11170 11701289	3^	NERV	Headache/ Headache	1	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 11170 11701291	3^	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
		NERV	Headache/ Headache	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
			Injection site pain/ Left Arm Injection Site Pain	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
			Pain/ Body Aches	2	02OCT2020	1/C	1	Yes		NA/TC	N	N/N
		MUSC	Arthralgia/ Joint Pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		NERV	Headache/ Headache	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 11170 11701293	3^	GENRL	Fatigue/ Fatigue	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1170 11701300	3^	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N	
			Injection site pain/ Injection Site Pain	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
16-55/ C459100 1 1170 11701303	3^	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N	
			MUSC	Myalgia/ Muscle Pain Generalized	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
			GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
			NERV	Headache/ Headache	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
			GENRL	Fatigue/ Fatigue	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
				Injection site pain/ Pain at Injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
			MUSC	Myalgia/ Generalized Muscle Pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
			NERV	Headache/ Headache	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1170 11701304	3^	GENRL	Injection site pain/ Pain at Injection Site	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1170 11701307	3^	GENRL	Injection site pain/ Pain at Injection Site	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	26SEP2020	16/3	1	Yes		NA	R (28SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		MUSC	Myalgia/ General Muscle Pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
			Pain in extremity/ Left Arm Pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		NERV	Headache/ Headache	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1170 11701310	3^	GENRL	Injection site pain/ Injection Site Pain	1	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1170 11701312	3^	NERV	Headache/ Headache	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Relative ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1170 11701313	3^	GENRL	Fatigue/ Fatigue	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ Injection Site Pain	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		MUSC	Arthralgia/ Generalized Joint Pain	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
			Injection site swelling/ Injection Site Swelling	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Chills/ Chills	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
			Fatigue/ Fatigue	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Chills/ Chills	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
			Injection site pain/ Pain at Injection Site	2	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/N
			Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1170 11701316	3^	NERV	Headache/ Headache	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		GASTR	Nausea/ Nausea	1	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)		
16-55/ C459100 1 1170 11701317	3^	GENRL	Fatigue/ Fatigue	1	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N		
			Pyrexia/ Fever	1	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N		
		MUSC	Myalgia/ Myalgias	1	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N		
		GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N		
			Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N		
		MUSC	Myalgia/ Muscle Pain	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N		
		GASTR	Dysphagia/ Difficulty Swallowing	1	15SEP2020	1/5	1	Yes		NA	R (19SEP2020)	N/N		
		16-55/ C459100 1 1170 11701318	3^	GENRL	Eructation/ Burping	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
					Chills/ Chills	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
					Fatigue/ Fatigue	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
Injection site erythema/ Injection Site Redness	1				15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N		
			Injection site pain/ Pain Injection Site	1	15SEP2020	1/5	1	Yes		NA	R (19SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Injection site swelling/ Injection Site Swelling	1	15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N
			Pyrexia/ Fever	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Arthralgia/ Generalized Joint Pain	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
			Myalgia/ Muscle Pain	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ Headache	1	18SEP2020	4/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	2	06OCT2020	1/33	1	Yes		NA	R (07NOV2020)	N/N
			Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
			Injection site erythema/ Redness at Injection Site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
			Injection site pain/ Pain at Injection Site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
			Injection site swelling/ Swelling at Injection Site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
			Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		MUSC	Arthralgia/ Joint Pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
			Myalgia/ Muscle Pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		NERV	Headache/ Headache	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701320	3^	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	16SEP2020	2/3	1	Yes		NA/TC	R (18SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	1	16SEP2020	2/3	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site erythema/ Redness at injection site	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 11170 11701321	3^	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/ Pain at injection site	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 11170 11701322	3^	GENRL	Chills/ Chills	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
			Fatigue/ Fatigue	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ Injection Site Pain	1	15SEP2020	1/5	1	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ Headache	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1170 11701325	3^†	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N	
			Pyrexia/ Fever	2	06OCT2020	1/3	1	Yes		NA/TC	R (08OCT2020)	N/N	
		MUSC	Myalgia/ Myalgias	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N	
		NERV	Headache/ Headache	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N	
		GASTR	Diarrhoea/ Diarrhea	2	17OCT2020	12/2	1	No	O	NA	R (18OCT2020)	N/N	
		GENRL	Injection site erythema/ Injection Site Redness	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
			Injection site pain/ Injection Site Pain	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
		3^	GENRL	Injection site pain/ Injection Site Pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
			GENRL	Injection site pain/ Pain at Injection Site	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		3^	GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		MUSC	Myalgia/ General Muscle Pain	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701340	3^	NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		NERV	Headache/ Headache	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Chills/ Chills	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Fatigue/ Fatigue	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 11170 11701343	3^	MUSC	Myalgia/ Generalized Muscle Pain	1	19SEP2020	3/4	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
			Injection site pain/ Injection Site Pain	1	18SEP2020	2/3	1	Yes		NA/TC	R (20SEP2020)	N/N
		GENRL	Injection site erythema/ Injection site redness	2	08OCT2020	1/15	1	Yes		NA/TC	R (22OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
MUSC	Myalgia/ Myalgias	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		UNC	INJECTION AT PAIN SITE@@/ Injection at Pain Site	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		GASTR	Vomiting/ vomiting	2	10OCT2020	3/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1170 11701348	3^	GENRL	Injection site pain/ Injection Site Pain	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1170 11701352	3^†	GENRL	Chills/ Chills	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1170 11701355	3^†	MUSC	Myalgia/ Muscle Pain	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100 1 1170 11701358	3^	GENRL	Injection site pain/ Injection Site Pain	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		MUSC	Muscle spasms/ Muscle Spasms	1	07OCT2020	17/C	1	Yes		NA	N	N/N
		NERV	Dizziness/ Dizziness	2	16OCT2020	5/5	1	No	O	NA	R (20OCT2020)	N/N
		EYE	Glaucoma/ Glaucoma	2	NOV2020	21/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701359	3^	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 11170 11701362	3^	GENRL	Injection site pain/ Injection Site Pain	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Chills/ Chills	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
		MUSC	Myalgia/ General Muscle Pain	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C459100 11170 11701370	3^	GASTR	Diarrhoea/ Diarrhea	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 11170 11701372	3^	MUSC	Myalgia/ Muscle Pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
		NERV	Headache/ Headache Pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 11170 11701373	3^	GENRL	Injection site pain/ Injection Site Pain	1	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ Pain at injection site	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		MUSC	Myalgia/ Muscle Pain	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Chills/ Chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
			Fatigue/ Fatigue	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 11171 11711014	3^	GENRL	Injection site pain/ Arm pain (at the injection site)	1	02SEP2020	21/3	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 11171 11711020	3^	GENRL	Fatigue/ Fatigue	2	06SEP2020	3/1	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 11171 11711021	3^	INFEC	Subcutaneous abscess/ Skin abscess (wrist)	2	14SEP2020	5/6	2	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C459100 11171 11711026	3^	MUSC	Neck pain/ Neck Pain	2	30SEP2020	28/17	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C459100 11171 11711027	3^	INJ&P	Muscle strain/ Lower back strain	2	18SEP2020	15/11	2	No	O	NA/TC	R (28SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11171 11711029	3^	GENRL	Pyrexia/ Fever	2	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
16-55/ C459100 11171 11711033	3^	GENRL	Fatigue/ Fatigue	1	14AUG2020	1/8	1	No	O	NA	R (21AUG2020)	N/N
16-55/ C459100 11171 11711034	3^	EAR	Vertigo/ Vertigo (Unknown cause)	2	09OCT2020	36/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 11171 11711039	3^	RESP	Nasal congestion/ Nasal Congestion	2	10OCT2020	39/6	2	No	O	NA/TC	R (15OCT2020)	N/N
16-55/ C459100 11171 11711050	3^	GENRL	Chills/ Chills	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
			Injection site pain/ Injection Site Pain [Left Arm Deltoid]	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C459100 11171 11711055	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	19AUG2020	2/3	1	Yes		NA	R (21AUG2020)	N/N
		GENRL	Chills/ Chills	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11171 11711060	3^	GENRL	Injection site pain/ Injection Site Pain [Left Arm Deltoid]	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11171 11711060	3^	GENRL	Injection site pain/ Soreness around injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11171 11711065	3^	GENRL	Injection site pain/ Soreness around injection site	2	09SEP2020	1/4	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 11171 11711067	3^	INV	Heart rate increased/ Elevated pulse rate	1	20AUG2020	3/1	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C459100 11171 11711069	3^	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 11171 11711073	3^	GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 11171 11711073	3^	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C459100 11171 11711085	3^	GENRL	Pain/ Body Aches (Generalized)	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 11171 11711088	3^	GENRL	Injection site pain/ Injection site pain	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C459100 11171 11711091	3^	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C459100 11171 11711093	3^	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		MUSC	Arthralgia/ LEFT SHOULDER PAIN	1	31AUG2020	12/12	2	No	O	NA/TC	R (11SEP2020)	N/N
			Neck pain/ WORSENING OF NECK PAIN	1	31AUG2020	12/12	2	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C459100 11171 11711128	3^	GENRL	Fatigue/ Fatigue	1	28AUG2020	3/5	1	Yes		NA	R (01SEP2020)	N/N
		NERV	Headache/ Headache	1	29AUG2020	4/4	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C459100 11171 11711130	3^	GASTR	Nausea/ Nausea	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11171 11711137	3^	GENRL	Chills/ Chills	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
			Injection site pain/ Injection Site Pain [Left Arm Deltoid]	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ Fever	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Soreness around injection site	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
			Pyrexia/ Fever	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 11171 11711146	3^	MUSC	Myalgia/ Myalgia	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 11171 11711151	3^	GENRL	Injection site erythema/ Redness to Injection Site	1	31AUG2020	1/6	1	Yes		NA	R (05SEP2020)	N/N
			Injection site swelling/ Swelling to Injection Site	1	31AUG2020	1/6	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 11171 11711154	3^	GENRL	Fatigue/ Fatigue	1	02SEP2020	3/4	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1171 11711158	3^	MUSC	Myalgia/ Muscle Pain	1	02SEP2020	3/4	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site erythema/ Erythema to injection site	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 1 1171 11711175	3^	NERV	Dizziness/ Dizziness	1	31AUG2020	1/4	1	No	O	NA	R (03SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	23SEP2020	1/2	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1171 11711191	3^	GENRL	Injection site pain/ Pain around injection site	1	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/N
		SKIN	Alopecia/ Hair loss	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 1 1171 11711200	3^	GENRL	Injection site pain/ Arm Pain (at the injection site)	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Pyrexia/ Fever	1	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1171 11711203	3^	GENRL	Pyrexia/ Fever	1	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11171 11711209	3^	GENRL	Injection site pain/ Soreness around injection site	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11171 11711211	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
		NERV	Headache/ Headache	1	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Headache	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
		CARD	Tachycardia/ Tachycardia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Chills/ Chills	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	2/1	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100 11171 11711223	3^	NERV	Headache/ Headache	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 11171 11711225	3^	MUSC	Pain in extremity/ Pain in Arm [Left]	1	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site erythema/ Redness around injection site	1	11SEP2020	1/6	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1171 11711236			Injection site pain/ Injection site pain	1	11SEP2020	1/5	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1171 11711242	3^	GENRL	Chills/ Chills	1	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
			Pyrexia/ Fever	1	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1171 11711246	3^	GENRL	Injection site erythema/ Erythema at injection site	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
			Injection site pain/ Soreness at Injection Site	1	11SEP2020	1/6	2	Yes		NA/TC	R (16SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
			Pain/ Body aches	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
			Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
		NERV	Headache/ Headache	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100	3^	MUSC	Myalgia/ Muscle aches, generalized	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1171 11711249 16-55/ C459100 1 1171 11711251	3^	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
			Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		MUSC	Myalgia/ Muscle Ache	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1171 11711252	3^	GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
			Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1171 11711260	3^	GENRL	Injection site pain/ Arm pain (at the injection site)	1	16SEP2020	1/2	1	Yes		NA/TCN	R (17SEP2020)	N/N
16-55/ C459100 1 1171 11711266	3^	GENRL	Injection site pain/ Left Arm pain (at the injection site)	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11171 11711271			Pain/ Body aches	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100 11171 11711274	3^	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ Soreness around injection site	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		NERV	Headache/ Headache	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 11171 11711281	3^	GENRL	Injection site pain/ Soreness around injection site	1	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		UNC	INJECTION SITE PAIN@@/ Injection site pain	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 11174 11741003	3^	NEOPL	Malignant melanoma/ right forearm melanoma	2	01OCT2020	11/8	1	No	O	NA/TCN	R (08OCT2020)	N/N
16-55/ C459100 11174 11741027	3^	MUSC	Periarthritis/ Adhesive Capsulitis left shoulder	2	23OCT2020	29/C	1	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11177 11771001	3^	NERV	Headache/ HEADACHE	2	16OCT2020	45/1	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C459100 11177 11771030	3^	NERV	Dizziness/ Dizziness	1	27AUG2020	15/4	2	No	O	NA	R (30AUG2020)	N/N
16-55/ C459100 11177 11771050	3^	GENRL	Fatigue/ FATIGUE	1	18AUG2020	2/29	1	No	O	NA	R (15SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
			Pyrexia/ FEVER	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C459100 11177 11771051	3^	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/4	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C459100 11177 11771066	3^	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C459100 11177 11771078	3^	GASTR	Diarrhoea/ DIARRHEA	1	29AUG2020	11/2	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11177 11771096 16-55/ C459100	3^	GENRL	Chills/ CHILLS	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
11177 11771105			Injection site pain/ PAIN AT INJECTION SITE (LEFT ARM)	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
			Pain/ BODY ACHES	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
			Pyrexia/ FEVER	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 11177 11771114	3^	GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	5/2	1	No	O	NA	R (26AUG2020)	N/N
		INFEC	Tooth infection/ TOOTH INFECTION	2	08OCT2020	28/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 11177 11771117	3^	GENRL	Pain/ Generalized Body Aches	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11177 11771119	3^	MUSC	Back pain/ BACK PAIN, INTERMITTENT	2	30SEP2020	17/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11177 11771155	3^	INFEC	Otitis externa/ EXTERNAL OTITIS, LEFT EAR	1	09SEP2020	15/10	2	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C459100 11177 11771156	3^	GENRL	Injection site pain/ Injection Site Pain	2	17SEP2020	2/24	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 11177 11771159	3^	GENRL	Pain/ WORSENING BODY ACHES	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
		INFEC	Sinusitis/ SINUS INFECTION	2	03OCT2020	19/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 11177 11771160	3^	GASTR	Nausea/ NAUSEA	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Pain/ GENERALIZED BODY ACHES	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11177 11771162	3^	GENRL	Injection site pain/ Injection Site Pain	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11177 11771166	3^	GENRL	Pyrexia/ FEVER	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11177 11771167	3^	GENRL	Pyrexia/ FEVER	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 11177 11771170	3^	GENRL	Pain/ BODY ACHES	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 11177 11771182	3^	GENRL	Pain/ BODY ACHES	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
			Pyrexia/ FEVER	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 11177 11771186	3^	GENRL	Pain/ Generalized Body Aches	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 11177 11771197	3^	GENRL	Pain/ Generalized Body Aches	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
			Pyrexia/ Fever	2	19SEP2020	2/1	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 11177 11771219	3^	GASTR	Abdominal pain upper/ Stomach Pain	1	08SEP2020	9/1	2	No	O	NA/TC	R (08SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11177 11771222	3^	GASTR	Nausea/ NAUSEA	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Pain/ BODY ACHES	2	21SEP2020	1/3	3	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 11177 11771224	3^	GENRL	Pain/ Generalized Body Aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 11177 11771236	3^	SURG	Salpingectomy/ Bilateral Salpingectomy	2	08OCT2020	16/1	2	No	O	NA/TC	R (08OCT2020)	N/N
16-55/ C459100 11177 11771241	3^	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ Chills	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
			Pain/ Generalized Body Aches	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 11177 11771242	3^	NERV	Headache/ Headache	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11177 11771254	3 [^]	MUSC	Myalgia/ Muscle Pain, Left Arm	1	03SEP2020	2/8	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11177 11771283	3 [^]	GENRL	Injection site pain/ Injection Site Pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 11177 11771297	3 [^]	MUSC	Muscle spasms/ MUSCLE CRAMP, LEFT SIDE OF BODY	1	10SEP2020	6/1	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Paraesthesia/ TINGLING SENSATION, LEFT ARM	1	10SEP2020	6/1	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11177 11771310	3 [^]	GENRL	Fatigue/ FATIGUE	1	08SEP2020	1/2	3	Yes		NA	R (09SEP2020)	N/N
			Pyrexia/ FEVER	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	1	08SEP2020	1/5	2	Yes		NA	R (12SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	29SEP2020	1/3	1	Yes		NA/TC	R (01OCT2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA	2	01OCT2020	3/1	1	Yes		NA/TC	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11177 11771323	3^	MUSC	Arthralgia/ Left Shoulder Pain	2	09OCT2020	10/C	1	No	O	NA	RG	N/N
16-55/ C459100 11177 11771330	3^	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 11177 11771331	3^	GENRL	Chills/ Chills	1	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 11177 11771361	3^	GENRL	Pyrexia/ FEVER	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 11177 11771393	3^	GENRL	Chills/ Chills	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 11177 11771418	3^	INFEC	Herpes zoster/ Shingles	1	11OCT2020	20/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 11177 11771445	3^	GENRL	Pain/ Generalized Body Aches	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		MUSC	Myalgia/ Muscle Aches, Neck and Shoulders	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1178 11781019	3^	GENRL	Injection site pain/ Injection Site Soreness	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Chills/ chills	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
			Fatigue/ fatigue	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
		3^	GENRL	Injection site pain/ soreness, left arm at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)
		GENRL	Chills/ chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
			Pain/ Achiness	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		3^	GENRL	Injection site pain/ Soreness at injection site.	1	27AUG2020	1/3	1	Yes		NA/TC	R (29AUG2020)
16-55/ C459100 1 1178 11781030		GENRL	Chills/ Chills	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1178 11781036	3^	GENRL	Injection site pain/ soreness at injection site	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		INJ&P	Road traffic accident/ Motor Vehicle Accident	1	14SEP2020	19/1	1	No	O	NA	R (14SEP2020)	N/N
		MUSC	Neck pain/ Neck pain	1	14SEP2020	19/3	1	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1178 11781043	3^	GENRL	Injection site pain/ Injection site soreness	1	28AUG2020	1/2	1	Yes		NA/TC	R (29AUG2020)	N/N
16-55/ C459100 1 1178 11781044	3^	NERV	Headache/ Headache	1	29AUG2020	2/2	1	Yes		NA/TC	R (30AUG2020)	N/N
		GENRL	Injection site pain/ Pain at injection site.	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1178 11781052	3^	GENRL	Malaise/ Malaise	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Fatigue/ fatigue	1	02SEP2020	3/2	2	Yes		NA	R (03SEP2020)	N/N
			Injection site pain/ Injection Site Muscle Soreness	1	02SEP2020	3/7	1	Yes		NA	R (08SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	1	02SEP2020	3/2	2	Yes		NA/TC	R (03SEP2020)	N/N
		GENRL	Chills/ Chills	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
			Fatigue/ Fatigue	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1178 11781054	3^	MUSC	Arthralgia/ Diffuse Arthralgia	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1178 11781055	3^	GENRL	Injection site pain/ Pain at injection site	1	31AUG2020	1/2	1	Yes		NA/TC	R (01SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	21SEP2020	1/4	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Chills/ chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1178 11781058	3^	NERV	Syncope/ syncope	1	18SEP2020	18/1	1	No	O	NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11178 11781061	3^	GENRL	Chills/ Chills	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
			Injection site pain/ injection site soreness	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
			MUSC Myalgia/ myalgias	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
			NERV Headache/ headache	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
			INJ&P Exposure during pregnancy/ partner exposure during pregnancy	1	02OCT2020	32/C		No	O	NA	UNK	N/N
16-55/ C459100 11178 11781067	3^	GENRL	MUSC Bone pain/ sternum pain	2	15OCT2020	2/C	1	No	O	NA	N	N/N
			Injection site pain/ Pain at injection site.	2	22SEP2020	2/4	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 11178 11781069	3^	GENRL	Injection site pain/ Tenderness at injection site.	2	22SEP2020	2/4	1	Yes		NA/TC	R (25SEP2020)	N/N
			Fatigue/ Fatigue	2	22SEP2020	1/5	1	Yes		NA	R (26SEP2020)	N/N
			Injection site pain/ Left deltoid injection site soreness	2	22SEP2020	1/5	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11178 11781073	3^	MUSC	Myalgia/ Body aches (generalized muscle aches)	2	22SEP2020	1/5	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	23SEP2020	2/4	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100 11178 11781074	3^	BLOOD	Lymphadenopathy/ bilateral axillary lymphadenopathy	2	25SEP2020	4/3	2	Yes		NA/TC	R (27SEP2020)	N/N
		SKIN	Rash/ left shoulder blade rash	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 11178 11781084	3^	INJ&P	Skin laceration/ right arch cut	1	05SEP2020	4/45	1	No	O	NA/TC	R (19OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/4	2	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
			Injection site erythema/ Redness at injection site	2	24SEP2020	2/7	1	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ Injection site pain	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11178 11781089	3^	GENRL	Pyrexia/ Fever	2	24SEP2020	2/3	1	Yes		NA/TC	R (26SEP2020)	N/N
			Injection site pain/ injection site pain	1	03SEP2020	1/5	1	Yes		NA	R (07SEP2020)	N/N
			Thirst/ increased sense of thirst	1	12SEP2020	10/C	1	No	O	NA	N	N/N
16-55/ C459100 11178 11781095	3^	GENRL	Pyrexia/ fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
			Injection site pain/ Pain at injection site	1	03SEP2020	1/4	2	Yes		NA	R (06SEP2020)	N/N
			Fatigue/ Fatigue	1	08SEP2020	6/3	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 11178 11781097	3^	SKIN	Fatigue/ fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Myalgia/ muscle aches	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
			Rash/ Rash, inner left arm, left fingers, right flank	1	14SEP2020	11/3	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100	3^	GENRL	Pyrexia/ Fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
			Injection site pain/ pain at injection site	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1178 11781098	3^	RESP	Pulmonary embolism/ Pulmonary embolism	2	20OCT2020	28/C	2	No	O	NA/TC	N	N/N
1 1178 11781104	3^	GENRL	Injection site erythema/ injection site redness	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
1 1178 11781107			Injection site pain/ injection site muscle soreness	1	04SEP2020	1/3	2	Yes		NA	R (06SEP2020)	N/N
			Injection site warmth/ injection site warmth	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ chills	1	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N
		BLOOD	Lymphadenopathy/ right axilla lymphadenopathy	1	16SEP2020	13/C	2	Yes		P/TC	N	Y/N
16-55/ C459100 1 1178 11781113	3^	MUSC	Pain in extremity/ Arm soreness - Right	1	08SEP2020	1/2	1	Yes		NA/TCN	R (09SEP2020)	N/N
		GENRL	Chills/ chills	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ injection site soreness	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
			Pain/ generalized body ache	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11178 11781121	3^	GENRL	Fatigue/ Fatigue	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
			Injection site pain/ Injection site pain	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
			GENRL Fatigue/ fatigue	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ left deltoid injection site soreness	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
			GENRL Feeling hot/ feeling of warmth - generalized	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 11178 11781128	3^	GENRL	Chills/ Chills	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Injection site pain/ Injection site muscle soreness	1	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
			MUSC Myalgia/ Myalgias	1	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
			GENRL Chills/ Chills	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
			Fatigue/ Fatigue	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ pain at injection site	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1178 11781130			Injection site pain/ Pain at injection site	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
			Injection site pain/ Injection site soreness	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
			Pain/ generalized body ache	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1178 11781133	3^	GENRL	Injection site pain/ Left deltoid soreness, injection site	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
		NERV	Headache/ headache	1	29SEP2020	21/3	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Injection site pain/ tenderness at injection site	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
			Malaise/ generalized malaise	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1178 11781135	3^	GENRL	Injection site pain/ Pain at injection site	1	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
		SKIN	Night sweats/ Night sweats	1	11SEP2020	3/1	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	30SEP2020	1/15	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11178 11781137	3^	GENRL	Injection site pain/ Tenderness at injection site	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 11178 11781145	3^	GENRL	Injection site pain/ Soreness at injection site*		10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Headache	1	23SEP2020	14/1	1	No	O	NA/TC	R (23SEP2020)	N/N
		GENRL	Injection site pain/ tenderness at injection site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11178 11781149	3^	GENRL	Injection site pain/ Injection site myalgia	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
		INJ&P	Skin laceration/ laceration, left index finger	2	22OCT2020	23/C	2	No	O	NA	N	N/N
16-55/ C459100 11178 11781150	3^	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Pain/ Body aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 11178 11781161	3^	GENRL	Pyrexia/ low grade temperature	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11178 11781163	3^	GENRL	Injection site pain/ Soreness at injection site	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Malaise/ General malaise	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100 11178 11781168	3^	GENRL	Injection site pain/ Injection site tenderness	1	14SEP2020	1/3	1	Yes		NA/TC	R (16SEP2020)	N/N
		GENRL	Injection site pain/ Tenderness at injection site	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 11178 11781170	3^	GENRL	Injection site pain/ pain at injection site	2	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/Y
		INFEC	Bacterial vaginosis/ bacterial vaginosis	1	14OCT2020	31/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 11178 11781175	3^	GENRL	Fatigue/ fatigue	1	15SEP2020	1/4	2	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ soreness at injection site	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ myalgia	1	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ headache	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11178 11781179	3^	GENRL	Chills/ chills	1	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
		GENRL	Chills/ chills	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ fever	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
		MUSC	Myalgia/ myalgias	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
		GENRL	Injection site pain/ injection site pain	1	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		GENRL	Chills/ rigors	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
			Injection site pain/ injection site pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
		NERV	Headache/ headache	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		16-55/ C459100 11178 11781181	3^	GENRL	Injection site pain/ Injection site tenderness - Right arm	1	16SEP2020	2/3	2	Yes		NA
GENRL	Pyrexia/ Fever	2		07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N	
MUSC	Myalgia/ Myalgias	2		07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 11178 11781182	3^	GASTR	Nausea/ Intermittent nausea	2	10OCT2020	6/C	1	No	O	NA	N	N/N
16-55/ C459100 11178 11781183	3^	GENRL	Chills/ chills	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
			Fatigue/ fatigue	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 11178 11781185	3^	GENRL	Injection site pruritus/ Itchiness at injection site	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 11178 11781186	3^	GENRL	Injection site pain/ injection site tenderness	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	19SEP2020	4/2	1	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ generalized myalgia	2	09OCT2020	4/3	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C459100 11178 11781187	3^	GENRL	Injection site pain/ Injection site soreness - Left deltoid*		16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11178 11781188	3^	GENRL	Injection site erythema/ Erythema at injection site	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ tenderness at injection site	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
		GASTR	Nausea/ nausea	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Chills/ chills	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
			Fatigue/ fatigue	1	16SEP2020	1/4	2	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ left arm pain at injection site	1	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		GENRL	Chills/ Chills	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
			Fatigue/ Fatigue	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 11178 11781197	3^	MUSC	Myalgia/ Myalgias	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	17SEP2020	2/5	1	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 11178 11781198	3^	GENRL	Fatigue/ fatigue	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N	
		GENRL	Fatigue/ fatigue	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N	
		NERV	Headache/ Headache	1	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N	
	16-55/ C459100 11178 11781208	3^	GENRL	Chills/ Chills	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
			MUSC	Myalgia/ Diffuse myalgias	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
			GENRL	Fatigue/ increased fatigue	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
			GENRL	Fatigue/ fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
			GENRL	Injection site pain/ Left deltoid soreness at injection site	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/Y
			GENRL	Injection site pain/ soreness at injection site	2	09OCT2020	1/4	1	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C459100 11178 11781214	3^	GENRL	Chills/ chills, intermittent	2	09OCT2020	1/5	1	Yes		NA/TC	R (13OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1178 11781217	3^	GENRL	Fatigue/ increased fatigue	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
		METAB	Decreased appetite/ decreased appetite	2	11OCT2020	3/3	1	Yes		NA	R (13OCT2020)	N/N
		GENRL	Injection site pain/ Injection site tenderness	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1178 11781218	3^	GENRL	Injection site pain/ injection site tenderness	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Arthralgia/ Left knee pain	2	20OCT2020	9/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C459100 1 1178 11781219	3^	GENRL	Injection site pain/ injection site tenderness	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Injection site pain/ tenderness at injection site	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1178 11781221	3^	GENRL	Fatigue/ fatigue	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
		GENRL	Pain/ generalized body ache	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ head ache	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1178 11781223	3^	GENRL	Injection site pain/ pain at injection site	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		INJ&P	Clavicle fracture/ right clavicle fracture	1	03OCT2020	13/C	1	No	O	NA/TC/TCN	N	N/N
16-55/ C459100 1 1178 11781224	3^	GENRL	Injection site pain/ soreness at injection site	1	21SEP2020	1/4	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		INFEC	Pharyngitis streptococcal/ Strep throat	1	28SEP2020	8/11	1	No	O	NA	R (08OCT2020)	N/N
		SKIN	Livedo reticularis/ livedo reticularis intermittent	1	28SEP2020	8/9	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C459100 1 1178 11781227	3^	GENRL	Malaise/ malaise	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1178 11781230	3^	GENRL	Injection site pain/ Tenderness at injection site	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	15OCT2020	3/3	1	Yes		NA	R (17OCT2020)	N/N
		NERV	Headache/ headache	2	15OCT2020	3/3	1	Yes		NA	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11178 11781233	3^	GENRL	Injection site pain/ soreness at injection site, left deltoid	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Malaise/ generalized malaise	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 11178 11781237	3^	GENRL	Injection site pain/ tenderness at injection site	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ injection site tenderness	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 11178 11781244	3^	GENRL	Injection site pain/ Pain at injection site.	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Pain in extremity/ Left intermittent forearm pain.	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Malaise/ malaise	2	13OCT2020	1/4	1	Yes		NA/TC	R (16OCT2020)	N/N
			Pyrexia/ fever	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ myalgias	2	13OCT2020	1/4	1	Yes		NA	R (16OCT2020)	N/N
		NERV	Headache/ headache	2	13OCT2020	1/4	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ pain at injection site	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11178 11781245	3^	GASTR	Diarrhoea/ diarrhea	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
11178 11781248		GENRL	Chills/ chills	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
			Fatigue/ fatigue	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
			Pyrexia/ fever	2	16OCT2020	1/3	1	Yes		NA/TC	R (18OCT2020)	N/N
		NERV	Headache/ headache	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 11178 11781249	3^	GENRL	Fatigue/ fatigue	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
		MUSC	Myalgia/ myalgias	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 11178 11781251	3^	GENRL	Injection site pain/ soreness, left arm beyond injection site	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 11178 11781253	3^	NERV	Headache/ Headache	1	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ Pain at injection site	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Pain/ Body ache	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Chills/ chills	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
			Pyrexia/ Fever	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
		MUSC	Myalgia/ mayalgias	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 11178 11781254	3^	GENRL	Injection site pain/ Soreness at injection site	1	25SEP2020	2/1	2	Yes		NA/TCN	R (25SEP2020)	N/N
16-55/ C459100 11178 11781263	3^	GENRL	Chills/ Chills	1	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
			Injection site pain/ Injection site pain	1	28SEP2020	1/3	2	Yes		NA	R (30SEP2020)	N/N
		SURG	Sinus operation/ Sinus drainage	1	01OCT2020	4/23	1	No	O	NA	R (23OCT2020)	N/N
		GENRL	Chills/ chills	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
			Pyrexia/ fever	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
		MUSC	Myalgia/ generalized muscle aches	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ headache	2	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C459100 11178 11781266	3^	GENRL	Injection site pain/ pain at injection site	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11178 11781268	3^	GENRL	Fatigue/ Fatigue	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		NERV	Headache/ Headache	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Chills/ chills	2	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
		MUSC	Myalgia/ Myalgias	2	21OCT2020	2/12	1	Yes		NA	R (01NOV2020)	N/N
		NERV	Headache/ Headache	2	21OCT2020	2/12	1	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C459100 11178 11781270	3^	GENRL	Injection site pain/ Soreness at injection site	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Vessel puncture site bruise/ Bruising at the site for blood draw	1	30SEP2020	2/10	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Injection site pain/ Soreness at injection site	2	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
		MUSC	Myalgia/ Myalgias	2	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11178 11781271	3^	GENRL	Injection site pain/ injection site soreness	1	29SEP2020	1/6	1	Yes		NA	R (04OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	19OCT2020	1/4	1	Yes		NA/TC	R (22OCT2020)	N/N
			Injection site pain/ pain at injection site	2	19OCT2020	1/4	1	Yes		NA	R (22OCT2020)	N/N
			Pyrexia/ Fever	2	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
			Pyrexia/ fever	2	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 11178 11781279	3^	GENRL	Injection site pain/ soreness at injection site, right deltoid	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 11178 11781284	3^	GENRL	Injection site bruising/ Bruising at injection site	1	06OCT2020	1/15	1	Yes		NA	R (20OCT2020)	N/N
		NERV	Headache/ Headache	1	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 11178 11781285	3^	GENRL	Injection site pain/ Tenderness at injection site	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
			Pain/ Body aches	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ Chills	2	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
			Pain/ Generalized body aches	2	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C459100 11178 11781288	3^	GENRL	Injection site pain/ pain at injection pain	1	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	27OCT2020	2/1	1	Yes		NA/TC	R (27OCT2020)	N/N
			MUSC	Myalgia/ Generalized myalgias	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)
16-55/ C459100 11178 11781291	3^	GENRL	Injection site pain/ Tenderness at injection site	1	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 11204 12041001	3^	GENRL	Injection site pain/ Injection Site Pain	1	24AUG2020	1/3	1	Yes		NA/TC	R (26AUG2020)	N/N
		GENRL	Pyrexia/ Fever	1	24AUG2020	1/2	1	Yes		NA/TC	R (25AUG2020)	N/N
			GASTR	Dyspepsia/ Heart Burn	1	12SEP2020	20/2	2	No	O	NA/TC	R (13SEP2020)
16-55/ C459100 11204 12041005	3^	GASTR	Retching/ gagging lasting 5-10 seconds, with second episode today	1	06SEP2020	13/2	1	No	O	NA	R (07SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1204 12041008	3^	IMMUN	Hypersensitivity/ allergies, normal per patient.	1	06SEP2020	13/2	1	No	O	NA	R (07SEP2020)	N/N
		GENRL	Pyrexia/ Fever	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
		MUSC	Myalgia/ Grade 1 Myalgias	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 1 1204 12041009	3^	GENRL	Fatigue/ fatigue	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1204 12041010	3^	NERV	Pyrexia/ Mild fever	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 1 1204 12041012	3^	GENRL	Chills/ chills	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1204 12041013		MUSC	Myalgia/ Muscle aches	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1204 12041015	3^	GENRL	Fatigue/ Fatigue	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ Muscle pain at injection site	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1204 12041017	3^	GENRL	Chills/ Chills	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
			Pyrexia/ Fever	2	28SEP2020	1/3	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1204 12041018	3^	MUSC	Back pain/ Back soreness	2	04OCT2020	7/2	1	Yes		NA/TC	R (05OCT2020)	N/N
16-55/ C459100 1 1204 12041020	3^	GENRL	Injection site pain/ Pain at the Injection Site	1	31AUG2020	1/3	2	Yes		NA/TC	R (02SEP2020)	N/N
16-55/ C459100 1 1204 12041021	3^	GENRL	Fatigue/ moderate to strong fatigue after the injection lasting days	1	01SEP2020	2/6	1	Yes		NA	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1204 12041023	3^	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		BLOOD	Lymphadenopathy/ swollen lymph node gland on neck	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
			Pyrexia/ Subjective Fever	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 1 1204 12041026	3^	GENRL	Chills/ chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Arthralgia/ Sore Left Shoulder	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		GASTR	Nausea/ nausea	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Chills/ Chills	2	22SEP2020	1/8	1	Yes		NA	R (29SEP2020)	N/N
			Fatigue/ Fatigue	2	22SEP2020	1/8	1	Yes		NA	R (29SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ myalgias	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
NERV	Headache/ Severe headache	2	22SEP2020	1/25	1	Yes		NA	R (16OCT2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1204 12041029	3^	NERV	Dizziness/ Dizziness	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1204 12041030	3^	GASTR	Diarrhoea/ non-bloody diarrhea x2 - his fiance who is not participating in the study also experience diarrhea	1	08SEP2020	7/1	1	No	O	NA	R (08SEP2020)	N/N
16-55/ C459100 1 1204 12041039	3^	GENRL	Chills/ chills	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
		SKIN	Hyperhidrosis/ sweats	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Chills/ Chills	1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N
			Fatigue/ Fatigue	1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1204 12041043	3^	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
		NERV	Dizziness/ Dizziness	1	18SEP2020	15/3	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1204 12041049	3^	GENRL	Vaccination site pain/ left arm pain (vac #2 injection site)	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Dizziness/ dizziness	2	29SEP2020	5/2	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Pyrexia/ low grade fever	1	09SEP2020	2/2	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1204 12041055	3^	GENRL	Pyrexia/ Low grade fever, maximum temp of 100.3 F	2	29SEP2020	1/3	1	Yes		NA/TC	R (01OCT2020)	N/N
		MUSC	Pain in extremity/ left arm pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Pain in extremity/ arm pain	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1204 12041058	3^	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	01OCT2020	3/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11204 12041059		MUSC	Myalgia/ Muscle aches	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 11204 12041064	3^	MUSC	Pain in extremity/ left arm pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11204 12041067	3^	GENRL	Vaccination site pain/ left arm pain (vac #2 site)	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 11204 12041071	3^	GENRL	Pyrexia/ Fever: Temp 101 F	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
		MUSC	Pain in extremity/ right arm pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ Headache	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 11204 12041072	3^	GASTR	Diarrhoea/ mild diarrhea	1	11SEP2020	3/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1204 12041073	3^	MUSC	Arthralgia/ left shoulder pain	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
		NERV	Migraine/ Migraine	1	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1204 12041075	3^	GENRL	Pyrexia/ Low grade fever, 102	1	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1204 12041077	3^	GENRL	Pyrexia/ Low grade fever, 100	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Influenza like illness/ Flu-like symptoms	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		GENRL	Vomiting/ Vomiting	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
			Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Fatigue	2	01OCT2020	2/5	1	Yes		NA	R (05OCT2020)	N/N
			Pain/ Generalized body aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Pyrexia/ fever 101.2	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vaccine Related ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1204 12041080	3^	NERV	Migraine/ Migraine	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		GENRL	Chills/ chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Fatigue/ fatigue	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1204 12041082	3^	INV	Vaccination site pain/ left arm soreness (post administration of vaccine #2)	2	30SEP2020	1/6	1	Yes		NA	R (05OCT2020)	N/N
			Body temperature increased/ elevated temperature, 100.1	1	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100 1 1204 12041086	3^	GENRL	Chills/ Chills	1	12SEP2020	3/1	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1204 12041091	3^	MUSC	Myalgia/ Muscle aches	1	12SEP2020	3/2	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Chills/ chills	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		GENRL	Pyrexia/ low grade fever, max temp of 100 F	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100	3^	MUSC	Pain in extremity/ left arm pain (post vaccine #2)	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1204 12041093		GENRL	Chills/ chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
			Fatigue/ fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1204 12041095	3^	VASC	Hot flush/ Feeling of hot flushes	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1204 12041097	3^	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1204 12041107	3^	GENRL	Injection site pain/ pain at injection site	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ headache	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1204 12041111	3^	GENRL	Fatigue/ Fatigue	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1204 12041112	3^	MUSC	Pain in extremity/ Pain left arm	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1204 12041121	3^	NERV	Headache/ Headache	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Injection site pain/ left upper arm pain (injection site)	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Pyrexia/ Low grade fever 100.3 F	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1204 12041123	3^	MUSC	Back pain/ mild back pain	1	20SEP2020	3/15	1	Yes		NA	R (04OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1204 12041124	3^		Vaccination site pain/ left arm soreness (vac #2 injection site)	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	28SEP2020	11/8	1	No	CD	NA	R (05OCT2020)	N/N
			Nausea/ Nausea	1	28SEP2020	11/8	1	No	CD	NA	R (05OCT2020)	N/N
16-55/ C459100	3^	GASTR	Diarrhoea/ Diarrhea	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Pyrexia/ Feeling hot/feverish	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/Y
		GENRL	Chills/ Chills	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1204 12041125	3^	GENRL	Fatigue/ fatigue	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
1 1204 12041128			Pain/ body aches	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
		MUSC	Pain in extremity/ left arm pain	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1204 12041133	3^	GENRL	Chills/ Chills	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1204 12041136	3^	GENRL	Injection site pain/ left arm soreness (vac#2 injection site)	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1204 12041138	3^	MUSC	Arthralgia/ opposite shoulder pain intermittent	1	22SEP2020	2/2	1	No	O	NA	R (23SEP2020)	N/N
			Myalgia/ muscle pain - abdominal	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1204 12041139	3^	GENRL	Injection site pain/ Muscle tenderness at injection site	2	12OCT2020	1/3	1	Yes		NA/TC	R (14OCT2020)	N/N	
			METAB	Polydipsia/ Polydipsia	2	12OCT2020	1/4	2	Yes		NA	R (15OCT2020)	N/N
			BLOOD	Lymphadenopathy/ Swollen submandibular lymph nodes	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
			GENRL	Pyrexia/ Low grade fever, 99.0	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
			GENRL	Injection site pain/ Pain left arm at injection site	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
			GENRL	Chills/ Chills	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1204 12041144	3^	GASTR	Pyrexia/ Fever (100.4)	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N	
			GENRL	Hypoaesthesia oral/ tongue numbness	1	24SEP2020	3/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1204 12041145	3^	GENRL	Fatigue/ fatigue	1	24SEP2020	3/2	1	Yes		NA	R (25SEP2020)	N/N	
			GENRL	Chills/ chills	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11204 12041147	3 [^]	MUSC	Pyrexia/ Low grade fever 100.3 F	1	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
			Pain in extremity/ arm pain	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Chills/ chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
			Pyrexia/ Fever; max temp of 102 F	2	14OCT2020	1/3	2	Yes		NA/TC	R (16OCT2020)	N/N
		GENRL	Injection site pain/ Muscle tenderness on injection site	1	23SEP2020	1/7	1	Yes		NA	R (29SEP2020)	N/N
		NERV	Fatigue/ Fatigue	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Headache/ Headache	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Chills/ Chills	1	30SEP2020	8/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 11204 12041153	3 [^]	GENRL	Chills/ Chills	1	30SEP2020	8/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 11204 12041154	3 ^{^†}	GENRL	Fatigue/ tired	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100	3 [^]	GENRL	Fatigue/ fatigue	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1204 12041155		NERV	Headache/ headache	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1204 12041167	3 [^]	GENRL	Injection site pain/ Muscle tenderness at injection site	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		GENRL	Vaccination site pain/ left arm soreness (vac #2 injection site)	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1204 12041170	3 [^]	MUSC	Myalgia/ Muscle aches	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Pyrexia/ Fever (100.4)	2	16OCT2020	1/2	1	Yes		NA/TC	R (17OCT2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	16OCT2020	1/2	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 1204 12041176	3 ^{^†}	GENRL	Pyrexia/ Subjective low grade fever	2	21OCT2020	3/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 1 1204 12041178	3 [^]	GENRL	Fatigue/ Fatigue	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1204 12041182		GENRL	Fatigue/ Fatigue	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N	
			Injection site pain/ Muscle tenderness at injection site	2	21OCT2020	1/6	1	Yes		NA	R (26OCT2020)	N/N	
	3 [†]	GENRL	Pyrexia/ Low grade fever, 100.6	2	22OCT2020	2/1	1	Yes		NA/TC	R (22OCT2020)	N/N	
		GENRL	Chills/ chills	2	04NOV2020	7/2	1	Yes		NA	R (05NOV2020)	N/N	
	3 [^]			Malaise/ malaise	2	04NOV2020	7/2	1	Yes		NA	R (05NOV2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	04NOV2020	7/2	1	Yes		NA	R (05NOV2020)	N/N	
		GENRL	Injection site pain/ pain at injection site	1	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N	
		METAB	Dehydration/ dehydration	2	31OCT2020	9/2	3	No	O	NA	R (01NOV2020)	N/N	
3 [^]	NERV	Syncope/ syncope	2	31OCT2020	9/2	3	No	O	NA	R (01NOV2020)	N/N		
	GENRL	Injection site pain/ pain at injection site	1	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1204 12041188	3 [†]	GENRL	Pyrexia/ Low grade fever, 100.4	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		NERV	Headache/ Headaches	2	26OCT2020	1/1	2	Yes		NA/TC	R (26OCT2020)	N/N
		GENRL	Injection site pain/ Muscle tenderness at injection site	2	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C459100 1 1204 12041191	3 [^]	RESP	Dyspnoea/ mild shortness of breath	1	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
		SKIN	Pruritus/ itching left arm	1	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
		SKIN	Pruritus/ itching left leg	1	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
		NERV	Headache/ Headache	2	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N
		GENRL	Injection site pain/ Muscle tenderness at injection site	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		GENRL	Pyrexia/ Low grade fever, 100.4	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1204 12041192	3^	SKIN	Rash/ Rash on the back of neck	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
		GENRL	Chills/ Chills	1	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1204 12041195	3^	GASTR	Diarrhoea/ Diarrhea	1	08OCT2020	3/4	1	Yes		NA	R (11OCT2020)	N/N
		GENRL	Pyrexia/ Fever	1	08OCT2020	3/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1204 12041195	3^	NERV	Headache/ Headache	1	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1204 12041203	3^	GENRL	Fatigue/ Fatigue	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1204 12041205	3^		Injection site pain/ Muscle tenderness at injection site	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Pyrexia/ Low grade fever, 100.2	2	30OCT2020	2/1	1	Yes		NA/TC	R (30OCT2020)	N/N
16-55/ C459100	3^	MUSC	Myalgia/ Muscle aches	2	30OCT2020	2/2	1	Yes		NA/TC	R (31OCT2020)	N/N
		GENRL	Chills/ Chills	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11204 12041209			Injection site pain/ Muscle tenderness at injection site	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
			Malaise/ Malaise	2	29OCT2020	1/5	1	Yes		NA	R (02NOV2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C459100 11219 12191001	3^	GENRL	Injection site reaction/ odd sensation posterior to injection site	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 11219 12191003	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	02OCT2020	2/5	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100 11219 12191013	3^	NERV	Headache/ Headache after hiking 22 miles	1	12OCT2020	5/1	1	No	O	NA/TC	R (12OCT2020)	N/N
		GENRL	Injection site pain/ muscle soreness at injection site	2	27OCT2020	1/3	2	Yes		NA	R (29OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	28OCT2020	2/1	3	Yes		NA	R (28OCT2020)	N/N
		MUSC	Myalgia/ generalized muscle soreness	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
		NERV	Headache/ headache	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1219 12191014	3^	GENRL	Fatigue/ fatigue	2	28OCT2020	2/1	3	Yes		NA	R (28OCT2020)	N/N
		MUSC	Myalgia/ generalized muscle soreness	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
		NERV	Headache/ headache	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C459100 1 1219 12191016	3^	GASTR	Nausea/ Nausea	2	01NOV2020	5/1	1	Yes		NA	R (01NOV2020)	N/N
		NERV	Headache/ Headache, waxing and waning	2	01NOV2020	5/10	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C459100 1 1223 12231022	3^	MUSC	Myalgia/ myalgias	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1223 12231024	3^	RESP	Throat irritation/ scratchy throat	2	28SEP2020	11/5	1	No	O	NA	R (02OCT2020)	N/N
16-55/ C459100 1 1223 12231034	3^	PSYCH	Abnormal dreams/ Vivid Dreams	1	29AUG2020	1/2	2	Yes		NA	R (30AUG2020)	N/N
		GENRL	Chills/ chills	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1223 12231050	3^	MUSC	Pyrexia/ fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			Myalgia/ myalgias	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			Headache/ Headache	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		IN FEC	Herpes zoster/ Shingles	2	29SEP2020	8/17	1	No	O	NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1223 12231057	3^	MUSC	Arthralgia/ Knee pain	2	18OCT2020	27/15	1	No	O	NA/TC	R (01NOV2020)	N/N
		GEN RL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Pyrexia/ Fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
NERV	Myalgia/ Myalgia		2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N	
16-55/ C459100 1 1223 12231062	3^	IN J&P	Post procedural swelling/ facelift swelling	2	13OCT2020	21/1	1	No	O	NA/TC	R (13OCT2020)	N/N
			Procedural pain/ pain from facelift	2	13OCT2020	21/13	2	No	O	NA	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1223 12231066	3^	GASTR	Diarrhoea/ diarrhea	2	27SEP2020	7/1	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ headache	2	27SEP2020	7/1	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1223 12231073	3^	GASTR	Nausea/ nausea	2	04OCT2020	13/2	2	No	O	NA	R (05OCT2020)	N/N
		NERV	Dizziness/ Dizziness	2	04OCT2020	13/2	2	No	O	NA	R (05OCT2020)	N/N
16-55/ C459100 1 1223 12231077	3^	MUSC	Arthralgia/ joint aches	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
			Myalgia/ muscle aches	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1223 12231090	3^	GENRL	Peripheral swelling/ left arm swelling	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/Y
		SKIN	Erythema/ Left arm redness	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/Y
16-55/ C459100 1 1223 12231094	3^	NERV	Headache/ headache	2	25SEP2020	1/1	2	Yes		NA/TC	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		SKIN	Hyperhidrosis/ sweats	1	25SEP2020	24/2	2	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1223 12231095	3^	MUSC	Arthralgia/ right elbow pain	2	30SEP2020	6/2	2	No	O	NA	R (01OCT2020)	N/N
16-55/ C459100 1 1223 12231112	3^	GENRL	Fatigue/ fatigue	2	20OCT2020	23/3	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C459100 1 1223 12231118	3^	GENRL	Chills/ chills	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
		MUSC	Pain in extremity/ left arm soreness	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1223 12231137	3^	GENRL	Fatigue/ fatigue	2	30SEP2020	1/3	1	Yes		NA/TC	R (02OCT2020)	N/N
		MUSC	Myalgia/ muscle pain	2	30SEP2020	1/3	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1223 12231145	3^	GASTR	Diarrhoea/ Diarrhea	1	11SEP2020	3/1	2	No	O	NA	R (11SEP2020)	N/N
		NERV	Tension headache/ tension headaches	2	14OCT2020	15/11	2	No	O	NA/TC	R (24OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1223 12231154	3^	GENRL	Chills/ chills*		10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
			Fatigue/ fatigue	1	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1223 12231157	3^	MUSC	Pain in extremity/ Exertional Left arm soreness	1	10SEP2020	1/4	3	Yes		NA/TC	R (13SEP2020)	N/N
		NERV	Headache/ Headache	1	10SEP2020	1/2	3	Yes		NA/TC	R (11SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
			Pyrexia/ mild fever	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1223 12231160	3^	GENRL	Fatigue/ fatigue	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Pain in extremity/ arm pain	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	07OCT2020	3/2	2	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1223 12231161	3^	GENRL	Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1223 12231166	3^	METAB	Gout/ exacerbation of gout in shoulder	1	04OCT2020	21/C	1	No	O	NA/TC	N	N/N
		VASC	Hypertensive urgency/ hypertensive urgency	2	28OCT2020	22/9	2	No	O	NA/TC	R (05NOV2020)	Y/N
16-55/ C459100 1 1223 12231175	3^	GENRL	Pyrexia/ fever	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1223 12231184	3^	GENRL	Chills/ chills	2	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1223 12231187	3^	GENRL	Fatigue/ fatigue	2	10OCT2020	5/1	2	Yes		NA	R (10OCT2020)	N/N
		NERV	Headache/ headache	2	10OCT2020	5/1	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1223 12231192	3^	GASTR	Nausea/ nausea	1	19SEP2020	2/1	3	Yes		NA/TCN	R (19SEP2020)	N/N
16-55/ C459100 1 1223 12231204	3^	GENRL	Chills/ chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
			Pain/ bodyaches	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1223 12231221	3^	NERV	Headache/ headache	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		RESP	Oropharyngeal pain/ sore throat	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea*		01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1223 12231226	3^	MUSC	Pain in extremity/ right arm soreness	1	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1224 12241010	3^	EYE	Lacrimation increased/ Watery eyes	2	02SEP2020	2/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1224 12241065	3^	RESP	Rhinorrhoea/ Runny Nose	2	02SEP2020	2/C	1	No	O	NA	N	N/N
		GASTR	Diarrhoea/ Diarrhea	1	24AUG2020	1/14	2	Yes		NA	R (06SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	24AUG2020	1/10	2	Yes		NA	R (02SEP2020)	N/N
		GENRL	Pyrexia/ Feverish Chills	1	24AUG2020	1/10	2	Yes		NA	R (02SEP2020)	N/N
		INV	Blood pressure increased/ Increased Blood Pressure	1	24AUG2020	1/18	2	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1224 12241079	3^	GENRL	Heart rate irregular/ Irregular Heart Rate	1	24AUG2020	1/18	2	Yes		P/W	R (10SEP2020)	N/N
			Asthenia/ Weakness	1	27AUG2020	3/2	1	No	O	NA	R (28AUG2020)	N/N
		PSYCH	Fatigue/ Fatigue	1	27AUG2020	3/2	1	No	O	NA	R (28AUG2020)	N/N
16-55/ C459100 1 1224 12241083	3^	CARD	Depression/ Depression	1	27AUG2020	3/2	1	No	O	NA	R (28AUG2020)	N/N
			Cardiac disorder/ Left Atrial Abnormality	1	01SEP2020	7/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1224 12241118	3^	GENRL	Chills/ Chills	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ Fever (100.6)	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
			NERV	Headache/ Headache	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)
16-55/ C459100 1 1224 12241119	3^	ENDO	Thyroid cyst/ Thyroid Nodule/Cyst	2	20OCT2020	29/C	2	No	O	NA/TC/TCN	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11224 12241121	3^	GENRL	Feeling abnormal/ Brain Fog	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			MUSC Myalgia/ Muscle Aches	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			NERV Headache/ Headache	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
			Lethargy/ Lethargy	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11224 12241126	3^	GASTR	Dry mouth/ Dry Mouth	1	02SEP2020	1/1	2	Yes		NA	R (02SEP2020)	N/Y
			GASTR Dry mouth/ Dry Mouth	2	23SEP2020	1/1	2	Yes		NA	R (23SEP2020)	N/Y
16-55/ C459100 11224 12241131	3^	GENRL	Pyrexia/ Low Grade Fever	1	08SEP2020	6/1	1	Yes		NA	R (08SEP2020)	N/N
			GENRL Pyrexia/ Low Grade Fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
			MUSC Myalgia/ Achy Muscles	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Exhaustion	1	07SEP2020	4/4	2	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1224 12241135	3^	RESP	Sinus congestion/ Sinus Congestion	1	18SEP2020	15/7	1	No	O	NA	R (24SEP2020)	N/N
1 1224 12241138	3^	NERV	Tremor/ Tremors	1	06AUG2020	2/2	2	Yes		NA/TC	R (07AUG2020)	N/N
1 1226 12261014	3^	RESP	Cough/ Dry cough	1	14AUG2020	9/28	1	No	O	NA	R (10SEP2020)	N/N
1 1226 12261027	3^	NERV	Headache/ Headache	2	28AUG2020	4/1	1	Yes		NA	R (28AUG2020)	N/N
1 1226 12261030	3^	GENRL	Fatigue/ Fatigue	1	18AUG2020	12/2	1	No	O	NA	R (19AUG2020)	N/N
		MUSC	Myalgia/ Muscular pain	2	28AUG2020	3/2	1	Yes		NA	R (29AUG2020)	N/N
		MUSC	Myalgia/ Muscular pain	2	30AUG2020	5/1	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100	3^	MUSC	Back pain/ Backache	2	29SEP2020	35/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261044	3^	MUSC	Back pain/ Backache	2	11SEP2020	17/9	2	No	O	NA/TC	R (19SEP2020)	N/N
1 1226 12261045	3^	GENRL	Pyrexia/ fever (38 C)	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
1 1226 12261049		NERV	Headache/ Headache	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1226 12261067	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		RENAL	Nephrolithiasis/ Worsening of nephrolithiasis	2	09NOV2020	70/3	3	No	O	NA/TC	R (11NOV2020)	Y/N
16-55/ C459100 1 1226 12261072	3^	MUSC	Myalgia/ Muscle pain (shoulders and neck, on the right body side)	1	18AUG2020	8/C	2	Yes		P/TC	RG	N/N
16-55/ C459100 1 1226 12261073	3^	INFEC	Rhinitis/ Coryza	1	03SEP2020	24/2	1	Yes		NA	R (04SEP2020)	N/N
		RESP	Nasal congestion/ Nasal congestion	2	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261074	3^	EYE	Blepharitis/ blepharitis	2	28SEP2020	25/3	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261076	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	18AUG2020	8/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1226 12261082	3^	GASTR	Nausea/ nausea	1	19AUG2020	9/1	1	No	O	NA/TC	R (19AUG2020)	N/N
		MUSC	Torticollis/ torticollis	1	24AUG2020	14/1	1	No	O	NA/TC	R (24AUG2020)	N/N
16-55/ C459100 1 1226 12261085	3^	GASTR	Diarrhoea/ diarrhea	2	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		MUSC	Arthralgia/ arthralgia	2	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 1 1226 12261088	3^	GASTR	Angular cheilitis/ Angular cheilitis	1	20AUG2020	10/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261104	3^	GENRL	Fatigue/ Fatigue	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		NERV	Headache/ Headache	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1226 12261106	3^	NERV	Headache/ Headache	1	21AUG2020	11/1	1	No	O	NA/TC	R (21AUG2020)	N/N
		REPRO	Dysmenorrhoea/ Menstrual cramps	1	22AUG2020	12/1	1	No	O	NA/TC	R (22AUG2020)	N/N
		GENRL	Fatigue/ fatigue	2	02SEP2020	2/3	3	Yes		NA	R (04SEP2020)	N/N
		MUSC	Arthralgia/ joint pain	2	02SEP2020	2/2	3	Yes		NA	R (03SEP2020)	N/N
			Myalgia/ muscle pain	2	02SEP2020	2/2	3	Yes		NA	R (03SEP2020)	N/N
		NERV	Headache/ headache	2	02SEP2020	2/3	3	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1226 12261118	3^	MUSC	Back pain/ back pain	2	16SEP2020	14/2	1	No	O	NA/TC	R (17SEP2020)	N/N
			Neck pain/ neck pain	2	16SEP2020	14/2	1	No	O	NA/TC	R (17SEP2020)	N/N
16-55/ C459100	3^	MUSC	Pain in extremity/ Pain in legs	1	19AUG2020	8/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261124												
16-55/ C459100	3^	MUSC	Back pain/ acute low back pain	1	20AUG2020	9/C	2	No	O	NA/TC	RG	N/N
1 1226 12261126												
16-55/ C459100	3^	INJ&P	Fall/ Bicycle fall	2	20SEP2020	18/1	3	No	O	NA/TCN	R (20SEP2020)	N/N
1 1226 12261137												
			Forearm fracture/ Right forearm fracture	2	20SEP2020	18/10	3	No	O	NA/TC/TCN	R (29SEP2020)	Y/N
16-55/ C459100	3^	GASTR	Dental caries/ Dental cavity	1	21AUG2020	10/6	1	No	O	NA/TCN	R (26AUG2020)	N/N
1 1226 12261139												
		INFEC	Gingivitis/ gingivitis	1	21AUG2020	10/8	1	No	O	NA/TC	R (28AUG2020)	N/N
16-55/ C459100	3^	NERV	Headache/ Headache	1	27AUG2020	16/1	1	No	O	NA	R (27AUG2020)	N/N
1 1226 12261144												
		NERV	Headache/ Headache	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100	3^	PSYCH	Anxiety disorder/ Anxiety disorder	1	14AUG2020	2/C	2	No	O	NA/TC	RG	N/N
1 1226 12261159												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261161	3^	MUSC	Back pain/ Left back pain	2	12OCT2020	40/3	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C459100 1 1226 12261164	3^	BLOOD	Lymph node pain/ sore left axillary lymph node	2	07SEP2020	5/15	1	Yes		NA	R (21SEP2020)	N/N
		MUSC	Back pain/ back pain on the left	2	07SEP2020	5/5	1	Yes		NA	R (11SEP2020)	N/N
			Pain in extremity/ left arm pain	2	07SEP2020	5/5	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1226 12261168	3^	GENRL	Injection site erythema/ Redness at injection site	2	18SEP2020	16/1	1	No	O	NA	R (18SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	18SEP2020	16/1	1	No	O	NA	R (18SEP2020)	N/N
16-55/ C459100 1 1226 12261174	3^	INFEC	Herpes zoster cutaneous disseminated/ multidermatomal herpes zoster	2	25OCT2020	53/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1226 12261178	3^	GASTR	Abdominal pain/ abdominal colic	2	30OCT2020	57/1	1	No	O	NA	R (30OCT2020)	N/N
16-55/ C459100 1 1226 12261189	3^	INFEC	Rhinitis/ coryza	2	26OCT2020	53/6	1	No	O	NA/TC	R (31OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Nasal congestion/ nasal congestion	2	26OCT2020	53/6	1	No	O	NA/TC	R (31OCT2020)	N/N
16-55/ C459100 1 1226 12261190	3^	BLOOD	Lymphadenopathy/ left axillary lymph node enlargement	2	06SEP2020	3/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1226 12261203	3^	PSYCH	Panic reaction/ Panic syndrome	1	22AUG2020	9/1	3	No	O	NA/TC	R (22AUG2020)	N/N
		METAB	Glucose tolerance impaired/ prediabetes	2	10SEP2020	7/C	1	No	O	NA/TC	RG	N/N
		MUSC	Arthralgia/ left knee arthralgia	2	29SEP2020	26/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1226 12261208	3^	GASTR	Abdominal pain/ Abdominal pain	2	12SEP2020	5/2	2	Yes		NA/TC	R (13SEP2020)	N/N
			Nausea/ Nausea	2	12SEP2020	5/2	2	Yes		NA/TC	R (13SEP2020)	N/N
		GASTR	Abdominal pain/ Abdominal pain (intermittent)	2	12OCT2020	35/C	2	No	O	NA/TC	RG	N/N
			Nausea/ Nausea (intermittent)	2	12OCT2020	35/27	2	No	O	NA/TC	R (07NOV2020)	N/N
16-55/ C459100 1 1226 12261214	3^	INFECTION	Ear infection/ otitis on the left	2	12SEP2020	5/5	1	No	O	NA/TC	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261217	3^	GENRL	Pyrexia/ Fever 38 C	2	11SEP2020	4/1	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1226 12261240	3^	NERV	Headache/ headache	2	09NOV2020	62/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1226 12261249	3^	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Chills/ Chills	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ pain at injection site	2	15SEP2020	1/C	2	Yes		NA	RG	N/N
		MUSC	Myalgia/ muscle pain	2	15SEP2020	1/C	2	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1226 12261254	3^	GASTR	Diarrhoea/ diarrhea	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
		GASTR	Abdominal pain/ abdominal pain	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		GASTR	Abdominal pain/ abdominal colic	2	16OCT2020	38/C	1	No	O	NA	RG	N/N
16-55/ C459100	3^	GENRL	Fatigue/ fatigue	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261264			Pyrexia/ FEVER (38,8 C)	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1226 12261273	3^	GENRL	Pain/ body pain	1	20AUG2020	2/2	2	Yes		NA	R (21AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1226 12261274	3^	GENRL	Injection site pain/ Pain on injection site	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C459100 1 1226 12261275	3^	GENRL	Injection site pain/ Pain at injection site	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
		GENRL	Pyrexia/ Fever	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100	3^	GENRL	Pyrexia/ Fever (38 C)	1	19AUG2020	1/1	1	Yes		NA/TC	R (19AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261276		GENRL	Injection site pain/ pain at injection site	1	20AUG2020	2/2	2	Yes		NA	R (21AUG2020)	N/N
		NERV	Headache/ headache	1	20AUG2020	2/2	1	Yes		NA/TC	R (21AUG2020)	N/N
		SKIN	Pruritus/ Diffuse itching	2	13SEP2020	3/7	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1226 12261280	3^	GENRL	Injection site pain/ pain at injection site	1	19AUG2020	1/2	1	Yes		NA/TC	R (20AUG2020)	N/N
		NERV	Headache/ headache	1	19AUG2020	1/2	1	Yes		NA/TC	R (20AUG2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ headache	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1226 12261282	3^	INFEC	Appendicitis/ Appendicitis	2	01OCT2020	22/3	3	No	O	NA/TC/TCN	R (03OCT2020)	Y/N
16-55/ C459100 1 1226 12261285	3^	INFEC	Sinusitis bacterial/ Bacterial sinusitis	2	20SEP2020	11/7	2	No	O	NA/TC	R (26SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ pain at injection site	1	20AUG2020	2/3	2	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261292		GENRL	Injection site pain/ pain at injection site	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1226 12261300	3^	RENAL	Renal colic/ Renal colic	1	29AUG2020	10/2	4	No	O	NA/TC/TCN	R (30AUG2020)	Y/N
		INFEC	Conjunctivitis/ Conjunctivitis	1	01SEP2020	13/7	1	No	O	NA/TC	R (07SEP2020)	N/N
16-55/ C459100 1 1226 12261301	3^	GENRL	Injection site pain/ Pain at injection site	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		MUSC	Arthralgia/ Joint pain	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
			Myalgia/ Muscle pain	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	2	14SEP2020	1/2	3	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1226 12261303	3^	GENRL	Injection site pain/ pain at the injection site	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C459100 1 1226 12261307	3^	GENRL	Injection site pain/ Pain at injection site	1	21AUG2020	2/3	2	Yes		NA	R (23AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ fever	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N
		MUSC	Myalgia/ myalgia	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N
		NERV	Headache/ headache	1	21AUG2020	2/2	2	Yes		NA/TC	R (22AUG2020)	N/N
16-55/ C459100 1 1226 12261308	3^	NERV	Headache/ Headache	2	24SEP2020	14/2	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C459100 1 1226 12261312	3^	MUSC	Myalgia/ Myalgia	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C459100 1 1226 12261314	3^	GENRL	Injection site pain/ pain at the injection site	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		MUSC	Arthralgia/ arthralgia	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1226 12261323	3^	GENRL	Injection site pain/ pain at injection site	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C459100	3^	MUSC	Arthralgia/ Joint pain	1	20AUG2020	1/9	3	Yes		NA/TC	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261328	3^	NERV	Headache/ headache	2	12SEP2020	1/1	2	Yes		NA/TC	R (12SEP2020)	N/N
1 1226 12261330	3^	RESP	Oropharyngeal pain/ sore throat	2	12OCT2020	22/1	1	No	O	NA	R (12OCT2020)	N/N
1 1226 12261331	3^	GENRL	Injection site oedema/ edema at injection site	2	21SEP2020	1/C	2	Yes		NA	RG	N/N
1 1226 12261332		MUSC	Myalgia/ muscle pain	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1226 12261337	3^	MUSC	Myalgia/ muscle pain	2	10SEP2020	2/C	2	Yes		NA/TC	RG	N/N
		NERV	Headache/ headache	2	10SEP2020	2/C	2	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1226 12261338	3^	GENRL	Injection site pain/ Pain at injecton site	1	22AUG2020	2/2	1	Yes		NA/TC	R (23AUG2020)	N/N
			Pain/ Body pain	1	22AUG2020	2/2	1	Yes		NA/TC	R (23AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Pyrexia/ Fever	1	22AUG2020	2/2	1	Yes		NA/TC	R (23AUG2020)	N/N
			Injection site pain/ Pain at injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1226 12261341	3^	GENRL	Chills/ chills	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		MUSC	Myalgia/ myalgia	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C459100 1 1226 12261347	3^	MUSC	Myalgia/ Muscle pain	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
		MUSC	Back pain/ Left back pain	2	19SEP2020	10/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1226 12261348	3^	GENRL	Injection site pain/ pain at injection site	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
		GENRL	Pyrexia/ Fever (38,8 C)	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C459100 1 1226 12261351	3^	MUSC	Myalgia/ Muscle pain	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	21AUG2020	1/3	2	Yes		NA/TC	R (23AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ Pain at injection site	2	10SEP2020	1/5	2	Yes		NA/TC	R (14SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C459100 1 1226 12261352	3^	GENRL	Injection site pain/ Pain at injection site	1	22AUG2020	2/1	2	Yes		NA/TC	R (22AUG2020)	N/N
		NERV	Headache/ Headache	1	22AUG2020	2/1	2	Yes		NA/TC	R (22AUG2020)	N/N
16-55/ C459100 1 1226 12261355	3^	GENRL	Pyrexia/ Fever (38.7 C)	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1226 12261358	3^	GENRL	Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Pyrexia/ fever (37.9C)	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1226 12261361	3^	GENRL	Application site reaction/ hyperemia at the application site	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1226 12261362	3^	GENRL	Injection site pain/ Pain at injection site	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N	
			Injection site erythema/ Erythema at injection site	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N	
			Injection site pain/ Pain at the injection site	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N	
			GENRL	Pain/ Body pain	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		3^	MUSC	Myalgia/ Muscle pain	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
			NERV	Headache/ Headache	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
		3^	GENRL	Injection site pain/ pain at the injection site	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
			GENRL	Pyrexia/ fever (38.3C)	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		3^	GENRL	Injection site pain/ Pain at injection site	1	24AUG2020	1/1	2	Yes		NA	R (24AUG2020)	N/N
16-55/ C459100 1 1226 12261375	3^	GENRL	Chills/ chills	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261379			Pyrexia/ Fever (38,7 C)	1	25AUG2020	2/2	2	Yes		NA/TC	R (26AUG2020)	N/N
		MUSC	Myalgia/ muscle pain	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N
16-55/ C459100 1 1226 12261382	3^	GENRL	Fatigue/ Tiredness	1	25AUG2020	2/3	2	Yes		NA/TC	R (27AUG2020)	N/N
			Injection site pain/ Pain at injection site	1	25AUG2020	2/3	2	Yes		NA/TC	R (27AUG2020)	N/N
			Pyrexia/ Fever	1	25AUG2020	2/3	2	Yes		NA/TC	R (27AUG2020)	N/N
		GENRL	Malaise/ Malaise	1	15SEP2020	23/2	2	Yes		NA	R (16SEP2020)	N/N
		GENRL	Pain/ Body pain	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ Fever	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1226 12261387	3^	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
		GENRL	Chills/ chills	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261390	3^	MUSC	Myalgia/ Muscle pain	2	14SEP2020	1/3	1	Yes		NA/TC	R (16SEP2020)	N/N
		MUSC	Back pain/ Backache	1	30AUG2020	7/3	2	No	O	NA/TC	R (01SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	15SEP2020	1/19	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Pyrexia/ Fever (38 C)	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Malaise/ Malaise	2	16SEP2020	2/28	2	Yes		NA	R (13OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea intermittent	2	18SEP2020	4/C	1	Yes		NA/TC	RG	N/N
		GENRL	Fatigue/ Fatigue	2	18SEP2020	4/26	2	Yes		NA	R (13OCT2020)	N/N
		METAB	Decreased appetite/ Inapetence	2	18SEP2020	4/26	2	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1226 12261391	3^	MUSC	Torticollis/ torticollis	1	13SEP2020	21/5	2	No	O	NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1226 12261392	3^	GENRL	Injection site pain/ Pain at injection site	1	24AUG2020	1/3	2	Yes		NA	R (26AUG2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	2/4	1	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261395		MUSC	Pain in extremity/ Right arm pain	2	14OCT2020	31/1	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C459100 1 1226 12261396	3^	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1226 12261399	3^	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 1 1226 12261404	3^	GENRL	Chills/ chills	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
			Pyrexia/ fever	2	14SEP2020	1/2	1	Yes		NA/TC	RS (15SEP2020)	N/N
16-55/ C459100 1 1226 12261408	3^	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	1/3	2	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 1 1226 12261409	3^	MUSC	Myalgia/ Myalgia	1	31AUG2020	7/3	2	Yes		NA/TC	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261411	3^	NERV	Headache/ Headache	1	31AUG2020	7/3	2	Yes		NA/TC	R (02SEP2020)	N/N
		SKIN	Rash pruritic/ Pruritic Papular eruption	1	08SEP2020	15/20	1	No	O	NA/TC	R (27SEP2020)	N/N
		GASTR	Vomiting/ Vomit	2	15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1226 12261413	3^	INFEC	Cystitis/ cystitis	2	20SEP2020	6/6	2	No	O	NA/TC	R (25SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	1/2	2	Yes		NA	R (26AUG2020)	N/N
		GENRL	Pyrexia/ Fever (39 C)	2	15SEP2020	1/2	3	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1226 12261416	3^	MUSC	Myalgia/ muscle pain	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ headache	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
		MUSC	Back pain/ backache	2	27SEP2020	13/4	3	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261417	3^	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	2/2	1	Yes		NA/TC	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261421	3^	BLOOD	Lymphadenopathy/ left axillary lymphadenomegaly	2	16SEP2020	2/5	2	Yes		NA/TC	R (20SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	16SEP2020	2/5	2	Yes		NA/TC	R (20SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	17SEP2020	3/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Pyrexia/ Fever (38,3 C)	1	26AUG2020	1/1	1	Yes		NA/TC	R (26AUG2020)	N/N
		GENRL	Chills/ Chills	1	27AUG2020	2/2	2	Yes		NA	R (28AUG2020)	N/N
		NERV	Headache/ Headache	1	28AUG2020	3/7	2	Yes		NA/TC	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	2/1	2	Yes		NA/TC	R (27AUG2020)	N/N
		METAB	Vitamin D deficiency/ Hypovitaminosis D	1	27AUG2020	2/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1226 12261428	3^	NERV	Headache/ Headache	1	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N
		NERV	Headache/ Headache	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261429	3^	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N
1 1226 12261430		NERV	Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N
		GENRL	Injection site pain/ Pain at the site of injection	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100	3^	GASTR	Diarrhoea/ Diarrhea	1	29AUG2020	4/1	1	Yes		NA	R (29AUG2020)	N/N
1 1226 12261432		GASTR	Diarrhoea/ Diarrhea	1	31AUG2020	6/1	1	Yes		NA	R (31AUG2020)	N/N
16-55/ C459100	3^	MUSC	Torticollis/ torticollis	2	02OCT2020	14/20	1	No	O	NA/TC	R (21OCT2020)	N/N
1 1226 12261433												
16-55/ C459100	3^	MUSC	Myalgia/ Myalgia	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
1 1226 12261436												
16-55/ C459100	3^	GENRL	Pyrexia/ Fever (38 C)	1	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261439			Vaccination site pain/ Pain at vaccination site	1	27AUG2020	2/1	2	Yes		NA/TC	R (27AUG2020)	N/N
16-55/ C459100 1 1226 12261442	3^	MUSC	Myalgia/ muscle pain	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Pain/ Body pain	2	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ Fever 38.5 C	2	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1226 12261444	3^	GENRL	Pyrexia/ Fever 38.5 C	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1226 12261448	3^	GENRL	Injection site pain/ Pain at the injection site	2	19SEP2020	1/3	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1226 12261449	3^	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 1 1226 12261451	3^	GENRL	Chills/ Chills	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261454	3^	NERV	Headache/ Headache	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	3^	MUSC	Myalgia/ Muscle pain	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
		INFEC	Pilonidal cyst/ Pilonidal cyst	2	01OCT2020	13/16	2	No	O	NA/TC	R (16OCT2020)	N/N
	3^	MUSC	Myalgia/ Muscle pain	2	20SEP2020	2/1	2	Yes		NA/TC	R (20SEP2020)	N/N
	3^	GENRL	Injection site pain/ Pain at injection site	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	3^	RESP	Oropharyngeal discomfort/ throat discomfort	2	22OCT2020	34/1	1	No	O	NA	R (22OCT2020)	N/N
	3^	GENRL	Fatigue/ Fatigue	2	23SEP2020	3/C	2	Yes		NA	RG	N/N
		NERV	Somnolence/ Somnolence	2	23SEP2020	3/C	2	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261470	3^	GASTR	Diarrhoea/ diarrhea	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	28AUG2020	2/7	2	Yes		NA/TC	R (03SEP2020)	N/N
		NERV	Headache/ headache	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	02SEP2020	7/2	3	Yes		NA/TC	R (03SEP2020)	N/N
16-55/ C459100 1 1226 12261471	3^	GENRL	Injection site pain/ Pain at injection site	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N
			Pyrexia/ Fever	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
			Pyrexia/ fever	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
		NERV	Headache/ headache	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100 1 1226 12261475	3^	GENRL	Fatigue/ fatigue	2	19SEP2020	1/1	1	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ headache	2	19SEP2020	1/1	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261480	3^	GENRL	Pyrexia/ fever 37.9 C	2	19SEP2020	1/1	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1226 12261482	3^	GENRL	Fatigue/ fatigue	1	28AUG2020	2/3	2	Yes		NA/TC	R (30AUG2020)	N/N
		NERV	Headache/ headache	1	28AUG2020	2/3	2	Yes		NA/TC	R (30AUG2020)	N/N
16-55/ C459100 1 1226 12261484	3^	GENRL	Injection site pain/ Pain at injection site	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1226 12261486	3^	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Chills/ chills	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ pain at injection site	2	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		NERV	Headache/ headache	2	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ fatigue	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261488			Injection site pain/ Pain at injection site	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
		GASTR	Vomiting/ Vomiting	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Chills/ Chills	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
			Fatigue/ Fatigue	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ Headache	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1226 12261491	3^	GENRL	Chills/ Chills	2	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
			Fatigue/ Fatigue	2	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
			Pyrexia/ Fever 38.5 C	2	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100 1 1226 12261492	3^	PSYCH	Insomnia/ Insomnia	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261495	3^	GENRL	Fatigue/ fatigue	2	19SEP2020	1/2	2	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ headache	1	28AUG2020	1/2	1	Yes		NA/TC	R (29AUG2020)	N/N
16-55/ C459100 1 1226 12261500	3^	GENRL	Injection site pain/ injection site pain	1	28AUG2020	1/1	1	Yes		NA/TC	R (28AUG2020)	N/N
16-55/ C459100 1 1226 12261501	3^	MUSC	Myalgia/ Muscle pain	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
		GENRL	Pyrexia/ fever (38 C)	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ Headache	1	28AUG2020	1/1	1	Yes		NA/TC	R (28AUG2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	2	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1226 12261502	3^	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261503	3^	NERV	Headache/ Headache	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	29AUG2020	2/1	2	Yes		NA	R (29AUG2020)	N/N
		RESP	Nasal congestion/ Nasal congestion	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1226 12261505	3^	RESP	Nasal congestion/ Nasal congestion	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Chills/ Chills	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 1 1226 12261511	3^	MUSC	Injection site pain/ Pain at injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
			Myalgia/ Muscle pain	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 1 1226 12261512	3^	MUSC	Myalgia/ Muscle pain	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261516	3^	GENRL	Fatigue/ Fatigue	1	06SEP2020	2/1	2	Yes		NA/TCN	R (06SEP2020)	N/N
		GENRL	Chills/ chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1226 12261517	3^	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Chills/ chills	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
			Fatigue/ fatigue	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ myalgia	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1226 12261518	3^	MUSC	Back pain/ Acute mechanical low back pain	2	14OCT2020	23/1	2	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1226 12261519	3^	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1226 12261520	3^	GENRL	Injection site pain/ Pain at injection site*		02SEP2020	-1/4	2	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261522	3^	GENRL	Injection site pain/ Pain at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1226 12261525	3^	GENRL	Injection site pain/ Pain in the injection	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Pain/ body pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1226 12261531	3^	GENRL	Chills/ Chills	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1226 12261535	3^	GENRL	Injection site oedema/ edema at injection site	1	06SEP2020	2/3	1	Yes		NA	R (08SEP2020)	N/N
			Injection site pain/ Pain at injection site	1	06SEP2020	2/3	2	Yes		NA/TC	R (08SEP2020)	N/N
			Malaise/ Malaise	1	06SEP2020	2/6	2	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ Headache	1	06SEP2020	2/6	2	Yes		NA	R (11SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	08SEP2020	4/4	2	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ fatigue	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
			Pain/ body pain	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
			Pyrexia/ fever (38.4C)	2	25SEP2020	2/2	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100 1 1226 12261538	3^	PSYCH	Panic disorder/ Panic disorder	2	17OCT2020	20/2	2	No	O	NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 1226 12261542	3^	GASTR	Diarrhoea/ diarrhea	1	10SEP2020	6/3	2	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site erythema/ erythema at the injection site	1	12SEP2020	8/4	1	Yes		NA/TC/TCN	R (15SEP2020)	N/N
			Injection site oedema/ edema at injection site	1	12SEP2020	8/4	1	Yes		NA/TC/TCN	R (15SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ Fever 38.5 C	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		MUSC	Pain in extremity/ Pain in both legs	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261545	3^	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/3	2	Yes		NA	R (07SEP2020)	N/N
		NERV	Headache/ headache	1	05SEP2020	1/3	2	Yes		NA/TC	R (07SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
		NERV	Headache/ headache	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
		BLOOD	Lymphadenopathy/ enlargement of left axillary lymph node	2	25SEP2020	2/34	1	Yes		NA	R (28OCT2020)	N/N
		GENRL	Pain/ Body pain	2	26SEP2020	3/1	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1226 12261551	3^	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/2	2	Yes		NA	R (06SEP2020)	N/N
		GENRL	Chills/ Chills	2	24SEP2020	1/1	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1226 12261553	3^	GENRL	Injection site pain/ pain at injection site	1	05SEP2020	1/4	1	Yes		NA	R (08SEP2020)	N/N
			Injection site swelling/ swelling at the injection site	1	05SEP2020	1/4	1	Yes		NA	R (08SEP2020)	N/N
		GENRL	Pyrexia/ Fever	1	06SEP2020	2/2	1	Yes		NA/TC	R (07SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261555		GASTR	Diarrhoea/ Diarrhea	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
		GENRL	Pyrexia/ fever (38.1 C)	2	26SEP2020	3/1	2	Yes		NA/TC	R (26SEP2020)	N/N
		GENRL	Injection site pruritus/ itching at the injection site	1	05SEP2020	1/2	1	Yes		NA	R (06SEP2020)	N/N
		INJ&P	Contusion/ Knee contusion	2	26OCT2020	33/C	1	No	O	NA/TC	RG	N/N
		GENRL	Injection site pain/ Pain at injection site	1	06SEP2020	2/1	2	Yes		NA	R (06SEP2020)	N/N
		GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Pyrexia/ Fever 38.5 C	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100 1 1226 12261560	3^	GENRL	Fatigue/ fatigue	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ headache	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1226 12261562	3^	NERV	Headache/ headache	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C459100 1 1226 12261564	3^	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/2	2	Yes		NA	R (06SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ fever (38.1C)	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Chills/ chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		METAB	Decreased appetite/ inappetence	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1226 12261567	3^	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 1 1226 12261568	3^	GENRL	Injection site swelling/ swelling at the injection site	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Neck pain/ neck pain	2	30SEP2020	6/2	1	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1226 12261569	3^	NERV	Headache/ Headache	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1226 12261571	3^	INJ&P	Cervical vertebral fracture/ Fracture of the fourth cervical vertebra	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N
			Contusion/ Bruises in various regions of the body	2	21OCT2020	27/10	2	No	O	NA/TC	R (30OCT2020)	N/N
			Road traffic accident/ hit by motorcycle	2	21OCT2020	27/1	3	No	O	NA	R (21OCT2020)	Y/N
			Skin abrasion/ Excoriations in various regions of the body	2	21OCT2020	27/10	2	No	O	NA/TC	R (30OCT2020)	N/N
			Spinal cord injury cervical/ Cervical spinal cord contusion	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N
		NERV	Subarachnoid haemorrhage/ Subarachnoid hemorrhage	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N
		RENAL	Subcapsular renal haematoma/ Peri-renal hematoma	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N
16-55/ C459100 1 1226 12261572	3^	GENRL	Chills/ chills	1	06SEP2020	2/2	2	Yes		NA/TC	R (07SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261574	3^	GENRL	Injection site pain/ pain at injection site	1	07SEP2020	3/2	1	Yes		NA	R (08SEP2020)	N/N
			Pyrexia/ fever (38.2 C)	1	07SEP2020	3/1	2	Yes		NA/TC	R (07SEP2020)	N/N
		MUSC	Myalgia/ myalgia	1	07SEP2020	3/2	1	Yes		NA	R (08SEP2020)	N/N
		INFEC	Rhinitis/ Coryza	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		GASTR	Diarrhoea/ diarrhea	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	25SEP2020	2/1	3	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ fever (38.5 C)	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
			GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/3	1	Yes		NA	R (07SEP2020)
16-55/ C459100 1 1226 12261577	3^	GENRL	Chills/ chill	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261578	3^	GASTR	Nausea/ nausea	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1226 12261579	3^	GASTR	Nausea/ Nausea	1	14SEP2020	10/1	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C459100 1 1226 12261582	3^	GENRL	Injection site pain/ Pain at injection site	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C459100 1 1226 12261583	3^	GENRL	Chills/ Chills	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	28SEP2020	1/3	2	Yes		NA/TC	R (30SEP2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	1	07SEP2020	1/2	2	Yes		NA	R (08SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Pain at the injection site	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		GASTR	Diarrhoea/ diarrhea	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261585	3^	GASTR	Diarrhoea/ Diarrhea	1	13SEP2020	7/1	1	Yes		NA	R (13SEP2020)	N/N
1 1226 12261586	3^	GASTR	Diarrhoea/ Diarrhea	1	09SEP2020	3/2	1	Yes		NA	R (10SEP2020)	N/N
1 1226 12261587	3^	GENRL	Injection site pain/ Pain at injection site	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N
1 1226 12261588	3^	GENRL	Injection site oedema/ Edema at injection site	1	08SEP2020	2/2	2	Yes		NA	R (09SEP2020)	N/N
			Injection site pain/ Pain at site injection	1	08SEP2020	2/2	2	Yes		NA	R (09SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N
			Injection site pain/ Pain at injection site	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1226 12261592	3^	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	2/2	2	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ FATIGUE	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N
			Malaise/ Malaise	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N
		NERV	Headache/ headache	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
		INFEC	Vulvovaginal candidiasis/ Vaginal candidiasis	2	01OCT2020	4/4	2	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 1226 12261593	3^	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261595	3^	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
			Injection site pain/ Pain at injection site	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1226 12261596	3^	GENRL	Pyrexia/ Fever	1	08SEP2020	2/1	1	Yes		NA/TC	R (08SEP2020)	N/N
		GENRL	Pyrexia/ Fever 38 C	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100	3^	NERV	Paraesthesia/ tingling in the left upper limb	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261597												
16-55/ C459100	3^	GENRL	Fatigue/ fatigue	1	07SEP2020	1/4	1	Yes		NA	R (10SEP2020)	N/N
1 1226 12261599												
		MUSC	Myalgia/ myalgia	1	07SEP2020	1/4	1	Yes		NA/TC	R (10SEP2020)	N/N
		EYE	Ulcerative keratitis/ corneal ulcer right eye	1	20SEP2020	14/8	2	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ fatigue	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N
1 1226 12261600												
16-55/ C459100	3^	MUSC	Myalgia/ Muscle pain	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N
1 1226 12261601												
		NERV	Headache/ Headache	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
		NERV	Headache/ Headache	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Pain at the injection site	1	07SEP2020	1/3	2	Yes		NA	R (09SEP2020)	N/N
1 1226 12261602												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ Pain at the injection site	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 1 1226 12261603	3^	NERV	Headache/ Headache	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1226 12261606	3^	GENRL	Asthenia/ Asthenia	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
			Pyrexia/ Fever 38 C	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261607	3^	GENRL	Injection site pain/ Pain at injection site	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	08SEP2020	2/1	1	Yes		NA	R (08SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
			Injection site erythema/ Erythema at the injection site	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ Pain at the injection site	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	2/1	1	Yes		NA	R (08SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261609	3^	GENRL	Injection site pain/ Pain at injection site	1	07SEP2020	1/4	1	Yes		NA	R (10SEP2020)	N/N
1 1226 12261612		GENRL	Injection site pain/ Pain at injection site	2	28SEP2020	1/4	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Injection site erythema/ Erythema at the injection site	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
			Injection site swelling/ Swelling at the injection site	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1226 12261614	3^	GENRL	Chills/ Chills	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
			Injection site pain/ Pain at the injection site	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 1 1226 12261618	3^	NERV	Headache/ Headache	2	17OCT2020	17/5	2	No	O	NA	R (21OCT2020)	N/N
16-55/ C459100 1 1226 12261619	3^	GENRL	Injection site pain/ Pain at the injection site	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	02OCT2020	3/2	2	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261621	3^	NERV	Headache/ Headache	2	02OCT2020	3/2	2	Yes		NA/TC	R (03OCT2020)	N/N
		GENRL	Chills/ chills	1	08SEP2020	2/3	2	Yes		NA	R (10SEP2020)	N/N
			Fatigue/ fatigue	1	08SEP2020	2/3	2	Yes		NA	R (10SEP2020)	N/N
			Injection site pain/ pain at injection site	1	08SEP2020	2/3	2	Yes		NA	R (10SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1226 12261623	3^	MUSC	Arthralgia/ Joint pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		GASTR	Nausea/ Nausea	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	11SEP2020	4/2	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1226 12261627	3^	MUSC	Myalgia/ muscle pain	1	11SEP2020	4/5	2	Yes		NA/TC	R (15SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
			Injection site pain/ pain at injection site	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261628	3^	NERV	Headache/ headache	1	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
		GASTR	Nausea/ nausea	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
			Vomiting/ vomiting	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	29SEP2020	2/3	2	Yes		NA	R (01OCT2020)	N/N
		MUSC	Myalgia/ muscle pain	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
		NERV	Headache/ headache	2	26OCT2020	29/2	2	No	O	NA/TC	R (27OCT2020)	N/N
		MUSC	Myalgia/ Muscles pain	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Injection site oedema/ Edema at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		VASC	Hypertension/ Systemic arterial hypertension	1	14SEP2020	7/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1226 12261630	3^											
16-55/ C459100 1 1226 12261632	3^	GENRL	Injection site pain/ Pain at the injection site	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261633	3^	GENRL	Chills/ Chills	2	30SEP2020	1/1	2	Yes		NA/TC	R (30SEP2020)	N/N
			Fatigue/ Fatigue	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
			Headache/ Headache	2	29SEP2020	1/1	1	Yes		NA/TC	R (29SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	09SEP2020	1/1	1	Yes		NA/TC	R (09SEP2020)	N/N
			Injection site pain/ pain at the injection site	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ pain at injection site	1	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
GASTR	Diarrhoea/ diarrhea	1	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N		
	Nausea/ nausea	1	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Arthralgia/ joint pain	1	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
			Myalgia/ muscle pain	1	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		NERV	Headache/ headache	1	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Nausea/ Nauseas	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		MUSC	Arthralgia/ Joint pain	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
			Myalgia/ Muscle pain	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1226 12261644	3^	GENRL	Injection site pain/ Pain at injection site	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1226 12261647	3^	MUSC	Myalgia/ muscle pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1226 12261649	3^	GASTR	Nausea/ nausea	1	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261651		GENRL	Fatigue/ fatigue	1	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
			Pyrexia/ fever	1	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
		INFEC	Urinary tract infection/ urinary tract infection	2	11OCT2020	12/C	1	No	O	NA/TC	RG	N/N
		GENRL	Fatigue/ Fatigue	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
		NERV	Headache/ headache	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	2/4	1	Yes		NA	R (04OCT2020)	N/N
		NERV	Headache/ headache	2	01OCT2020	2/4	1	Yes		NA	R (04OCT2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261654	3^	GENRL	Pyrexia/ Fever (38.7 C)	2	29SEP2020	1/2	2	Yes		NA/TC	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261657	3^	GENRL	Injection site pain/ Pain at injection site	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1226 12261661	3^	GENRL	Injection site erythema/ erythema at the injection site	1	11SEP2020	1/5	1	Yes		NA	R (15SEP2020)	N/N
			Injection site pain/ pain at injection site	1	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	14SEP2020	4/3	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Fatigue/ Tiredness	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
		MUSC	Pain in extremity/ Right arm pain	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1226 12261665	3^	GENRL	Fatigue/ Fatigue	1	12SEP2020	1/1	2	Yes		NA	R (12SEP2020)	N/N
			Injection site pain/ Pain at the injection site	1	12SEP2020	1/2	2	Yes		NA	R (13SEP2020)	N/N
		GENRL	Asthenia/ Asthenia	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
			Pyrexia/ Fever	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		NERV	Headache/ Headache	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261666	3^	INV	Body temperature increased/ elevated body temperature (37.8 C)	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1226 12261667	3^	GENRL	Injection site pain/ Injection site pain	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1226 12261670	3^	GENRL	Injection site pain/ Pain at the injection site	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ headache	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 1226 12261673	3^	GENRL	Fatigue/ fatigue	1	12SEP2020	1/5	2	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ pain at injection site	1	12SEP2020	1/5	2	Yes		NA/TC	R (16SEP2020)	N/N
		GENRL	Pyrexia/ Fever 38.2 C	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C459100	3^	VASC	Hypertension/ Systemic arterial hypertension	1	19SEP2020	8/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261675	3^	GENRL	Fatigue/ Fatigue	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
1 1226 12261677		GENRL	Fatigue/ Fatigue	2	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1226 12261679	3^	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Chills/ Chills	2	03OCT2020	2/2	3	Yes		NA/TC	R (04OCT2020)	N/N
			Injection site pain/ Pain at injection site	2	03OCT2020	2/2	3	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 1226 12261680	3^	NERV	Headache/ headache	1	13SEP2020	2/1	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Asthenia/ Asthenia	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
			Injection site pain/ Pain at the injection site	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261681	3^	NERV	Headache/ Headache	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	14SEP2020	3/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1226 12261683	3^	SURG	Vasectomy/ Vasectomy	2	23OCT2020	22/1	1	No	O	NA/TC	R (23OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/2	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100 1 1226 12261686	3^	MUSC	Myalgia/ myalgia	1	12SEP2020	1/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		GENRL	Pyrexia/ Fever 38 C	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261690	3^	MUSC	Pain in extremity/ Left arm pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/3	2	Yes		NA	R (14SEP2020)	N/N
		GENRL	Chills/ chills	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
			Pyrexia/ fever (38 C)	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		MUSC	Myalgia/ muscle pain	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1226 12261691	3^	NERV	Headache/ headache	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Pyrexia/ Fever 38.2 C	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1226 12261695	3^	MUSC	Myalgia/ Myalgia	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
		INV	Body temperature increased/ Increased oral temperature 37,8 C	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
		GASTR	Abdominal pain/ Abdominal pain	2	05OCT2020	4/7	1	No	O	NA/TC	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261696	3^	GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/2	2	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1226 12261697	3^	GENRL	Injection site pain/ Pain at injection site	1	12SEP2020	1/2	3	Yes		NA	R (13SEP2020)	N/N
		NERV	Headache/ Headache	1	12SEP2020	1/2	3	Yes		NA/TC	R (13SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	13SEP2020	2/1	2	Yes		NA	R (13SEP2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1226 12261699	3^	GASTR	Diarrhoea/ Diarrhea	2	06OCT2020	2/1	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1226 12261703	3^	NERV	Headache/ Headache	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
		GENRL	Chills/ Chills	2	06OCT2020	2/1	2	Yes		NA	R (06OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	06OCT2020	2/1	2	Yes		NA/TC	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261705	3^	GASTR	Abdominal pain/ Colic abdominal pain	1	16SEP2020	3/2	1	Yes		NA/TC	R (17SEP2020)	N/N
			Diarrhoea/ Diarrhea	1	16SEP2020	3/2	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1226 12261706	3^	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		NERV	Headache/ Headache	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		RESP	Oropharyngeal pain/ Sore throat	2	06OCT2020	2/2	1	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1226 12261707	3^	GENRL	Pyrexia/ fever (37,8 C)	2	05OCT2020	1/1	1	Yes		NA/TC	R (05OCT2020)	N/N
		BLOOD	Lymphadenopathy/ axillary lymphadenopathy in the left arm	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1226 12261710	3^	INFEC	Cystitis/ cystitis	1	18SEP2020	5/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	1	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261712												
16-55/ C459100	3^	BLOOD	Lymphadenopathy/ Axillary adenomegaly	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
1 1226 12261714		GENRL	Injection site pain/ Pain at injection site	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
		NERV	Headache/ Headache	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	1	14SEP2020	1/3	2	Yes		NA/TCN	R (16SEP2020)	N/N
1 1226 12261715		GENRL	Fatigue/ Fatigue	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
			Pyrexia/ Fever (38.5 C)	2	05OCT2020	1/2	2	Yes		NA/TC	R (06OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N
		NERV	Headache/ Headache	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	1	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N
1 1226 12261716		MUSC	Myalgia/ muscle pain	1	14SEP2020	1/1	1	Yes		NA/TC	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261718	3^	GENRL	Injection site pain/ Pain at the injection site	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
		GENRL	Injection site erythema/ Erythema at the injection site	2	07OCT2020	3/4	1	Yes		NA	R (10OCT2020)	N/N
		NERV	Headache/ Headache	1	23SEP2020	10/1	1	No	O	NA/TC	R (23SEP2020)	N/N
		INV	Body temperature increased/ Body temperature elevated 37.8 C	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
		GENRL	Injection site erythema/ Hyperemia at injection site	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1226 12261721	3^	GENRL	Injection site pain/ pain at injection site	2	05OCT2020	1/4	1	Yes		NA/TC	R (08OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1226 12261724	3^	GENRL	Injection site pain/ pain at injection site	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261726	3^	GENRL	Injection site erythema/ Erythema at injection site	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1226 12261729	3^	GENRL	Chills/ chills	2	06OCT2020	1/C	2	Yes		NA/TC	RG	N/N
		NERV	Headache/ headache	2	06OCT2020	1/C	2	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1226 12261730	3^	GENRL	Injection site pain/ Pain at the injection site	1	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
		PSYCH	Insomnia/ Insomnia	1	16SEP2020	2/4	2	Yes		NA/TC	R (19SEP2020)	N/N
		MUSC	Arthralgia/ Joint pain	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
			Myalgia/ Muscle pain	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1226 12261731	3^	GASTR	Diarrhoea/ diarrhea	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100	3^	GENRL	Pyrexia/ Fever 38.2 C	2	07OCT2020	2/1	2	Yes		NA/TC	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261733		NERV	Headache/ Headache	2	08OCT2020	3/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		GASTR	Dysphagia/ SWALLOWING DIFFICULT	2	23OCT2020	18/2	1	No	O	NA/TC	R (24OCT2020)	N/N
16-55/ C459100 1 1226 12261737	3^	GENRL	Injection site pain/ pain at injection site*		15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ headache	1	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1226 12261741	3^	GENRL	Chills/ Chills	1	16SEP2020	1/1	2	Yes		NA	R (16SEP2020)	N/N
			Pyrexia/ Fever (38,5 C)	1	16SEP2020	1/1	2	Yes		NA/TC	R (16SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	17SEP2020	2/3	2	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ Headache	1	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
		SKIN	Urticaria/ Urticaria localised (neck and forearm plaques, 1 plaque in each of these locations)	1	19SEP2020	4/11	1	No	O	NA	R (29SEP2020)	N/N
		GENRL	Chills/ Chills	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261742	3^	GENRL	Injection site pain/ Pain at the injection site	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ fever (39.5 C)	2	07OCT2020	2/1	3	Yes		NA/TC	R (07OCT2020)	N/N
			MUSC Myalgia/ muscle pain	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1226 12261745	3^	NEOPL	Leydig cell tumour of the testis/ Leydig cell tumor in left testicle	1	23SEP2020	8/15	2	No	O	NA	R (07OCT2020)	Y/N
16-55/ C459100 1 1226 12261746	3^	GENRL	Injection site pain/ Pain at injection site	1	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
			GENRL Fatigue/ Fatigue	2	07OCT2020	2/1	2	Yes		NA/TC	R (07OCT2020)	N/N
			GENRL Pyrexia/ Fever 38.5	2	07OCT2020	2/1	2	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1226 12261747	3^	GENRL	Injection site erythema/ erythema at injection site	1	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
			GENRL Injection site pain/ pain at injection site	1	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261751	3^	GENRL	Injection site erythema/ Erythema at injection site	1	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N
			Injection site oedema/ edema at injection site	1	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ Pain at injection site	1	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
		MUSC	Myalgia/ muscle pain	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
		MUSC	Arthralgia/ joint pain in hands	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1226 12261753	3^	NERV	Joint swelling/ joint swelling in hands	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
			Headache/ Headache	1	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1226 12261759	3^	GASTR	Diarrhoea/ diarrhea	1	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
			GENRL	Fatigue/ fatigue	1	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)
			Injection site pain/ pain at injection site	1	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Pyrexia/ fever	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1226 12261763	3^	GENRL	Injection site pain/ Pain at the injection site	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1226 12261764	3^	GENRL	Injection site pain/ Pain at the injection site	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1226 12261765	3^	NERV	Headache/ Headache	1	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1226 12261766	3^	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
			Pyrexia/ Fever 38.7 C	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1226 12261767	3^	GENRL	Fatigue/ Fatigue	1	19SEP2020	3/3	2	Yes		NA	R (21SEP2020)	N/N
		NERV	Headache/ Headache	1	19SEP2020	3/3	2	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261768	3^	GASTR	Diarrhoea/ Diarrhea	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1226 12261769	3^	GENRL	Injection site pruritus/ Pruritus at the injection site	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
		NERV	Idiopathic intracranial hypertension/ idiopathic intracranial hypertension	2	22OCT2020	16/9	3	No	O	NA/TC/TCN	R (30OCT2020)	Y/N
		INFEC	Postoperative wound infection/ surgical site infection	2	03NOV2020	28/C	3	No	O	NA/TC	RG	Y/N
16-55/ C459100 1 1226 12261770	3^	GENRL	Injection site pain/ Pain at the injection site	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1226 12261771	3^	GENRL	Fatigue/ Tiredness	1	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1226 12261778	3^	GENRL	Pyrexia/ Fever (38.5 C)	1	17SEP2020	1/1	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100	3^	NERV	Headache/ Headache	1	19SEP2020	3/2	1	Yes		NA/TC	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261779		GASTR	Diarrhoea/ Diarrhea	2	17OCT2020	11/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1226 12261784	3^	GENRL	Injection site pain/ Pain at injection site	1	18SEP2020	2/8	2	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	08OCT2020	2/1	2	Yes		NA/TC	R (08OCT2020)	N/N
			Pyrexia/ fever (38.4C)	2	08OCT2020	2/1	2	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1226 12261790	3^	GENRL	Injection site erythema/ erythema at injection site	1	17SEP2020	1/12	2	Yes		NA	R (28SEP2020)	N/N
			Injection site pain/ pain at injection site	1	17SEP2020	1/12	2	Yes		NA	R (28SEP2020)	N/N
		GENRL	Pyrexia/ Fever 38.2	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
		METAB	Decreased appetite/ inapetence	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1226 12261791	3^	GENRL	Injection site pain/ Pain at injection site	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Relative ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261792	3^	GENRL	Pyrexia/ fever (38 C)	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
			MUSC	Myalgia/ muscle pain	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)
16-55/ C459100 1 1226 12261795	3^	GENRL	Injection site pain/ Pain at injection site	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1226 12261796	3^	GENRL	Injection site pain/ Pain at injection site	2	07OCT2020	1/5	2	Yes		NA	R (11OCT2020)	N/N
		GENRL	Pyrexia/ Fever 38.1 C	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1226 12261797	3^	GENRL	Injection site pain/ Pain at the injection site	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Asthenia/ Weakness	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1226 12261797	3^	MUSC	Myalgia/ Muscle pain	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261800	3^	GENRL	Chills/ chills	1	17SEP2020	1/6	1	Yes		NA	R (22SEP2020)	N/N
			Injection site erythema/ erythema at injection site	1	17SEP2020	1/6	1	Yes		NA	R (22SEP2020)	N/N
			Injection site pain/ pain at injection site	1	17SEP2020	1/6	1	Yes		NA	R (22SEP2020)	N/N
			Pyrexia/ fever	1	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	1	17SEP2020	1/6	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1226 12261802	3^	GENRL	Fatigue/ Fatigue	1	21SEP2020	5/1	2	Yes		NA	R (21SEP2020)	N/N
			NERV	Headache/ Headache	1	21SEP2020	5/1	2	Yes		NA	R (21SEP2020)
16-55/ C459100 1 1226 12261803	3^	GENRL	Injection site pain/ pain at injection site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1226 12261806	3^	GENRL	Chills/ Chills	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
			Fatigue/ Fatigue	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261809	3^	METAB	Decreased appetite/ Inapetence	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ Muscular pain	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ Headache	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Pyrexia/ Fever 38.2 C	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
		GENRL	Pyrexia/ Fever (38.1 C)	1	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1226 12261815	3^	GENRL	Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
			Pyrexia/ Fever (38 C)	2	08OCT2020	1/3	1	Yes		NA/TC	R (10OCT2020)	N/N
		GASTR	Abdominal pain upper/ epigastric pain	2	09OCT2020	2/4	2	Yes		NA	R (12OCT2020)	N/N
			Diarrhoea/ diarrhea	2	09OCT2020	2/4	2	Yes		NA	R (12OCT2020)	N/N
	NERV	Headache/ headache	2	09OCT2020	2/6	2	Yes		NA/TC	R (14OCT2020)	N/N	
	SKIN	Skin lesion/ pruritic erimatos lesions on the face	2	13OCT2020	6/2	1	Yes		NA	R (14OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261819	3^	INV	Body temperature increased/ Body temperature increased 37.3 C	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1226 12261820	3^	GENRL	Fatigue/ Fatigue	2	08OCT2020	1/1	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1226 12261823	3^	RESP	Rhinorrhoea/ runny nose	1	28SEP2020	11/1	1	No	O	NA	R (28SEP2020)	N/N
16-55/ C459100 1 1226 12261824	3^	GENRL	Injection site pain/ pain at injection site	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
		GENRL	Chills/ chills	2	08OCT2020	1/1	1	Yes		NA/TC	R (08OCT2020)	N/N
			Injection site pain/ pain at injection site	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1226 12261826	3^	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
			Pyrexia/ Fever 38 C	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261827	3^	MUSC	Myalgia/ muscle pain	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ headache	1	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1226 12261831	3^	NERV	Headache/ Headache	2	09OCT2020	2/1	2	Yes		NA/TC	R (09OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1226 12261833	3^	GENRL	Chills/ Chills	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1226 12261835	3^	MUSC	Myalgia/ Muscle pain	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N
		MUSC	Arthralgia/ Joint pain	1	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1226 12261838	3^	GENRL	Myalgia/ Myalgia	1	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N
			Pyrexia/ Fever(39 C)	2	08OCT2020	1/3	2	Yes		NA/TC	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261839	3^	GENRL	Fatigue/ fatigue	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
			Injection site erythema/ erythema at the injection site	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
			MUSC Myalgia/ Muscle pain	1	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N
			GENRL Injection site pain/ Pain at injection site	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/Y
			MUSC Myalgia/ myalgia	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/Y
16-55/ C459100 1 1226 12261840	3^	GASTR	Abdominal pain/ Intermittent abdominal colic	2	24OCT2020	17/7	1	No	O	NA	R (30OCT2020)	N/N
16-55/ C459100 1 1226 12261842	3^	GASTR	Diarrhoea/ Diarrhea	2	10OCT2020	3/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1226 12261845	3^	GENRL	Injection site pain/ pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		GENRL	Asthenia/ asthenia	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261846	3^	GENRL	Injection site pain/ Pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GASTR	Diarrhoea/ diarrhea	1	24SEP2020	7/1	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1226 12261847	3^	GENRL	Injection site pain/ pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1226 12261850	3^	GENRL	Injection site pain/ pain at injection site	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1226 12261853	3^	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ Pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ Headache	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	2	09OCT2020	1/3	2	Yes		NA/TC	R (11OCT2020)	N/N
			Pyrexia/ Fever 38 C	2	09OCT2020	1/3	2	Yes		NA/TC	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261854	3^	GENRL	Injection site pain/ Pain at the injection site	2	10OCT2020	2/C	1	Yes		NA/TC	RG	N/N
			Malaise/ Malaise	2	10OCT2020	2/C	1	Yes		NA/TC	RG	N/N
		MUSC	Myalgia/ Muscle pain	2	10OCT2020	2/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1226 12261858	3^	GENRL	Fatigue/ fatigue	1	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ pain at injection site	1	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ myalgia	1	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
		INV	Body temperature increased/ Increased body temperature (37.5)	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
		MUSC	Myalgia/ muscle pain	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1226 12261860	3^	GENRL	Injection site erythema/ erythema at site injection	1	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
			Injection site pain/ pain at injection site	1	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100	3^	GASTR	Abdominal pain upper/ Epigastric pain	1	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261863												
16-55/ C459100 1 1226 12261864	3^	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement	2	10OCT2020	2/6	2	Yes		NA/TC	R (15OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	10OCT2020	2/2	2	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C459100 1 1226 12261865	3^	NERV	Headache/ Headache	1	20SEP2020	2/4	2	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	10OCT2020	2/5	2	Yes		NA	R (14OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	12OCT2020	4/3	2	Yes		NA/TC	R (14OCT2020)	N/N
			Flatulence/ Flatulence	2	12OCT2020	4/3	2	Yes		NA/TC	R (14OCT2020)	N/N
		MUSC	Arthralgia/ Generalized joint pain	2	12OCT2020	4/3	2	Yes		NA/TC	R (14OCT2020)	N/N
			Myalgia/ Muscle pain	2	12OCT2020	4/3	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1226 12261867	3^	GENRL	Injection site pain/ Pain at injection site	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		GENRL	Pyrexia/ Fever (39 C)	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261868	3^	MUSC	Myalgia/ Muscle pain	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N
		NERV	Headache/ Headache	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1226 12261869	3^	GENRL	Fatigue/ Fatigue	1	19SEP2020	1/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1226 12261873	3^	MUSC	Myalgia/ Muscle pain	1	19SEP2020	1/1	1	Yes		NA	R (19SEP2020)	N/N
		MUSC	Neck pain/ Cervicalgia	1	08OCT2020	20/4	2	No	O	NA/TC	R (11OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
			Injection site pain/ Pain at injection site	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1226 12261875	3^	GENRL	Pyrexia/ Fever 38.1 C	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
			Fatigue/ Fatigue	1	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ chills	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
			Fatigue/ fatigue	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
			Injection site pain/ pain at injection site	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1226 12261876	3^	NERV	Headache/ Headache	1	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1226 12261877	3^	NERV	Headache/ Headache	2	08NOV2020	31/1	1	No	O	NA/TC	R (08NOV2020)	N/N
16-55/ C459100 1 1226 12261878	3^	GENRL	Injection site pain/ pain at injection site	1	19SEP2020	1/3	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Chills/ Chills	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
			Injection site pain/ Pain at injection site	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
			Pyrexia/ Fever (38 C)	2	08OCT2020	1/2	2	Yes		NA/TC/TCN	R (09OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100	3^	GENRL	Pyrexia/ fever (38.4C)	2	14OCT2020	1/1	1	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261880	3^	GENRL	Injection site pain/ Pain at injection site	1	26SEP2020	2/1	2	Yes		NA/TC	R (26SEP2020)	N/N
1 1226 12261881		MUSC	Myalgia/ Muscle pain	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100	3^	GASTR	Diarrhoea/ diarrhea	1	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
1 1226 12261882		GENRL	Injection site pain/ pain at injection site	1	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C459100	3^	GASTR	Abdominal pain/ abdominal colic	1	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
1 1226 12261884		GENRL	Chills/ Chills	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ headache	1	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100	3^	GENRL	Pyrexia/ Fever	1	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
1 1226 12261887												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INV	Body temperature increased/ Body temperature increased 37.5 C	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1226 12261888	3^	GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1226 12261898	3^	MUSC	Myalgia/ Muscle pain	2	16OCT2020	3/4	1	Yes		NA	R (19OCT2020)	N/N
16-55/ C459100 1 1226 12261900	3^	GENRL	Injection site pain/ Pain at injection site	1	25SEP2020	1/4	2	Yes		NA/TC	R (28SEP2020)	N/N
		GENRL	Chills/ Chills	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
			Fatigue/ Fatigue	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1226 12261902	3^	GENRL	Injection site pain/ Pain at the injection site	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1226 12261908	3^	GENRL	Injection site pain/ Pain at the injection site	1	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261912	3^	GENRL	Injection site pain/ Pain at injection site	1	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
		NERV	Headache/ Headache	1	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261918	3^	EYE	Keratitis/ Ocular keratitis	1	04OCT2020	7/8	1	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C459100 1 1226 12261919	3^	GENRL	Injection site pain/ Pain at the injection site	2	19OCT2020	1/3	1	Yes		NA	R (21OCT2020)	N/N
		GENRL	Pain/ Body pain	2	20OCT2020	2/2	2	Yes		NA/TC	R (21OCT2020)	N/N
			Pyrexia/ Fever	2	20OCT2020	2/2	2	Yes		NA/TC	R (21OCT2020)	N/N
		NERV	Headache/ Headache	2	20OCT2020	2/2	2	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 1 1226 12261922	3^	GASTR	Diarrhoea/ Diarrhea	1	11OCT2020	14/2	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C459100 1 1226 12261923	3^	GASTR	Diarrhoea/ Diarrhea	2	23OCT2020	3/C	2	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261928	3^	GENRL	Injection site pain/ Pain at injection site	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
			Malaise/ Malaise	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261929	3^	NERV	Headache/ Headache	2	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 1 1226 12261930	3^	GENRL	Fatigue/ Fatigue	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ Pain at the injection site	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261934	3^	GENRL	Injection site pain/ Pain at injection site	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 1 1226 12261935	3^	NERV	Headache/ Headache	1	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261936	3^	GENRL	Injection site pain/ pain at injection site	1	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Muscle pain	2	21OCT2020	2/1	2	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 1 1226 12261938	3^	NERV	Headache/ Headache	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261939	3^	GENRL	Chills/ chills	1	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ pain at injection site	1	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
			Malaise/ malaise	1	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261942	3^	MUSC	Myalgia/ Muscle pain	1	30SEP2020	2/2	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1226 12261945	3^	GENRL	Fatigue/ fatigue	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Myalgia/ myalgia	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261947	3^	GENRL	Injection site pain/ Pain at injection site	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261952	3^	GENRL	Malaise/ malaise	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
			Injection site pain/ pain at injection site	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ Fever (38 C)	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1226 12261954	3^	MUSC	Myalgia/ muscle pain	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ headache	1	01OCT2020	2/C	1	Yes		NA	RG	N/N
		GASTR	Diarrhoea/ Diarrhea	1	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1226 12261956	3^	GENRL	Injection site pain/ Pain at the injection site	1	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Asthenia/ weakness	2	04NOV2020	1/C	1	Yes		NA	RG	N/N
		NERV	Fatigue/ fatigue	2	04NOV2020	1/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1226 12261956	3^	NERV	Headache/ Headache	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
		GENRL	Chills/ chills	2	22OCT2020	2/C	1	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261960	3^	MUSC	Pyrexia/ fever (38 C)	2	22OCT2020	2/C	1	Yes		NA/TC	RG	N/N
			Myalgia/ muscle pain	2	22OCT2020	2/C	1	Yes		NA	RG	N/N
		NERV	Headache/ Headache	1	03OCT2020	4/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1226 12261961	3^	GASTR	Nausea/ Nauseas	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1226 12261962	3^	MUSC	Arthralgia/ joint pain	2	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C459100 1 1226 12261963	3^	NERV	Myalgia/ muscle pain	2	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
			Headache/ headache	2	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
		SKIN	Skin lesion/ Linear erythematous lesions in the anterior thoracic region	2	22OCT2020	2/C	1	No	O	NA	RG	N/N
		INFEC	Rhinitis/ Coryza	2	25OCT2020	5/1	1	No	O	NA	R (25OCT2020)	N/N
		RESP	Nasal congestion/ Nasal congestion	2	25OCT2020	5/1	1	No	O	NA	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261964	3^	GENRL	Fatigue/ fatigue	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		NERV	Headache/ headache	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C459100 1 1226 12261966	3^	MUSC	Myalgia/ Muscle pain	2	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
		NERV	Headache/ Headache	2	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
16-55/ C459100 1 1226 12261968	3^	GENRL	Injection site pain/ pain at injection site	1	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		NERV	Headache/ headache	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
		NERV	Headache/ Headache	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C459100 1 1226 12261972	3^	GENRL	Capsular contracture associated with breast implant/ Capsular contracture in breast implants	1	08OCT2020	9/C	2	No	O	NA	RG	N/N
			Medical device site granuloma/ Granuloma in breast implants	1	08OCT2020	9/C	2	No	O	NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261976	3^	GENRL	Chills/ chills	2	22OCT2020	1/1	2	Yes		NA/TC	R (22OCT2020)	N/N
			Injection site pain/ pain at injection site	2	22OCT2020	1/C	2	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1226 12261978	3^	GENRL	Injection site pain/ Pain at injection site	1	01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1226 12261981	3^	GENRL	Fatigue/ Fatigue	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ Pain at the injection site	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ Headache	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1226 12261983	3^	GENRL	Injection site pain/ Pain at the injection site	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1226 12261988	3^	GENRL	Injection site pain/ Pain at the injection site	1	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1226 12261995	3^	MUSC	Myalgia/ Muscle pain	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12261998	3^	GENRL	Injection site pain/ Pain at the injection site	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Malaise/ Malaise	1	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ Headache	1	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1226 12261999	3^	GENRL	Injection site pain/ pain at injection site	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
			Pyrexia/ Fever (38C)	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1226 12262001	3^	GENRL	Malaise/ Malaise	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
			Pain/ Body pain	1	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
			Pyrexia/ Fever 38.5 C	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1226 12262002	3^	GENRL	Injection site pain/ pain at injection site	1	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
			Malaise/ malaise	1	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12262012	3^	NERV	Headache/ headache	1	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		GENRL	Fatigue/ fatigue	1	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N
	3^	NERV	Headache/ Headache	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		GASTR	Toothache/ toothache	2	27OCT2020	7/C	2	No	O	NA/TC	RG	N/N
		GENRL	Injection site pain/ Pain at the injection site	2	21OCT2020	1/5	2	Yes		NA/TC	R (25OCT2020)	N/N
16-55/ C459100 1 1226 12262017	3^	GENRL	Injection site erythema/ Erythema at the injection site	2	22OCT2020	2/4	2	Yes		NA/TC	R (25OCT2020)	N/N
		GENRL	Injection site oedema/ Edema at the injection site	2	22OCT2020	2/4	2	Yes		NA/TC	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12262018	3^	GENRL	Pyrexia/ Fever 38.7 C	2	22OCT2020	2/1	2	Yes		NA/TC	R (22OCT2020)	N/N
			Pyrexia/ fever (38 C)	2	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C459100 1 1226 12262019	3^	MUSC	Myalgia/ muscle pain	2	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
		MUSC	Arthralgia/ Joint pain in the right knee	1	04OCT2020	3/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1226 12262021	3^	GENRL	Chills/ chills	1	02OCT2020	1/1	2	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ headache	1	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1226 12262023	3^	MUSC	Arthralgia/ joint pain	1	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	02OCT2020	1/5	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100	3^	MUSC	Arthralgia/ Arthralgia	1	02OCT2020	1/5	2	Yes		NA	R (06OCT2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	1	03OCT2020	1/2	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12262026		GENRL	Chills/ Chills	1	04OCT2020	2/1	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1226 12262029	3^	GASTR	Diarrhoea/ Diarrhea	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N
			Nausea/ Nausea	1	04OCT2020	2/3	2	Yes		NA/TC	R (06OCT2020)	N/N
		NERV	Headache/ Headache	1	04OCT2020	2/3	2	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1226 12262034	3^	GENRL	Fatigue/ fatigue	1	03OCT2020	1/3	1	Yes		NA	R (05OCT2020)	N/N
			Malaise/ malaise	1	03OCT2020	1/3	1	Yes		NA	R (05OCT2020)	N/N
		MUSC	Myalgia/ muscle pain	1	03OCT2020	1/3	1	Yes		NA	R (05OCT2020)	N/N
		NERV	Headache/ headache	1	04OCT2020	2/2	1	Yes		NA	R (05OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
			Injection site pain/ Pain at the injection site	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
			Pyrexia/ Fever 38.4 C	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12262037	3^	MUSC	Myalgia/ Muscle pain	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	2	26OCT2020	1/C	1	Yes		NA	RG	N/N
		INV	Body temperature increased/ Body temperature increased 37.6 C	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C459100 1 1226 12262039	3^	MUSC	Myalgia/ Myalgia	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	04OCT2020	2/8	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1226 12262040	3^	NERV	Headache/ Headache	1	04OCT2020	2/1	1	Yes		NA	R (04OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	03OCT2020	1/8	2	Yes		NA	R (10OCT2020)	N/N
		GENRL	Chills/ Chills	2	24OCT2020	2/7	2	Yes		NA/TC	R (30OCT2020)	N/N
16-55/ C459100	3^	MUSC	Myalgia/ Muscle pain	2	24OCT2020	2/7	2	Yes		NA	R (30OCT2020)	N/N
		NERV	Headache/ Headache	2	24OCT2020	2/7	2	Yes		NA	R (30OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	03OCT2020	1/4	1	Yes		NA	R (06OCT2020)	N/N
		GENRL	Chills/ Chills	2	24OCT2020	2/7	2	Yes		NA/TC	R (30OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12262042		NERV	Headache/ Headache	1	04OCT2020	2/2	1	Yes		NA/TC	R (05OCT2020)	N/N
16-55/ C459100 1 1226 12262044	3^	GENRL	Fatigue/ Tiredness	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N
			Injection site pain/ Pain at injection site	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N
			Malaise/ Malaise	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N
		NERV	Headache/ Headache	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N
		GENRL	Chills/ Chills	2	26OCT2020	1/C	1	Yes		NA/TC	RG	N/N
			Injection site pain/ Pain at the injection site	2	26OCT2020	1/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1226 12262045	3^	NERV	Headache/ Headache	1	04OCT2020	2/4	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1226 12262046	3^	GENRL	Pyrexia/ Fever (38,9 C)	2	26OCT2020	1/1	2	Yes		NA/TC	R (26OCT2020)	N/N
16-55/ C459100	3^	GASTR	Nausea/ nausea	1	04OCT2020	2/2	1	Yes		NA	R (05OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12262048	3^	INV	Body temperature increased/ Increased body temperature (37.7 C)	2	23OCT2020	1/2	1	Yes		NA/TC	R (24OCT2020)	N/N
1 1226 12262050		NERV	Headache/ Headache	2	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C459100 1 1226 12262051	3^	GENRL	Injection site pain/ pain at injection site	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
		MUSC	Myalgia/ muscle pain	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C459100 1 1226 12262058	3^	GENRL	Injection site pain/ pain at injection site	1	03OCT2020	1/2	1	Yes		NA	R (04OCT2020)	N/N
		GENRL	Pyrexia/ Fever 38 C	2	26OCT2020	1/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1226 12262059	3^	GASTR	Diarrhoea/ Diarrhea	1	03OCT2020	1/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1226 12262064	3^	GENRL	Injection site pain/ pain at injection site	1	03OCT2020	1/4	2	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ fatigue	1	04OCT2020	2/2	2	Yes		NA	R (05OCT2020)	N/N
16-55/ C459100 1 1226 12262065	3^	GENRL	Injection site pain/ Pain at injection site	1	03OCT2020	1/2	2	Yes		NA	R (04OCT2020)	N/N
			Malaise/ Malaise	1	03OCT2020	1/2	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1226 12262067	3^	MUSC	Pain in extremity/ Pain at right foot	1	10OCT2020	8/1	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1226 12262068	3^	GENRL	Injection site pain/ Pain at the injection site	1	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
		NERV	Headache/ Headache	1	14OCT2020	10/2	2	No	O	NA	R (15OCT2020)	N/N
16-55/ C459100 1 1226 12262071	3^	NERV	Headache/ Headache	1	05OCT2020	1/1	1	Yes		NA/TC	R (05OCT2020)	N/N
16-55/ C459100 1 1226 12262072	3^	EYE	Eye pain/ retro eye pain	1	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		GENRL	Fatigue/ fatigue	1	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1226 12262076	3^	NERV	Injection site pain/ Pain at the injection site	1	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N	
			Headache/ headache	1	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N	
		GENRL	Injection site pain/ pain at injection site	1	05OCT2020	1/2	1	Yes			NA	R (06OCT2020)	N/Y
			GASTR	Diarrhoea/ diarrhea	1	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1226 12262079	3^	GENRL	Injection site pain/ Pain at the injection site	1	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N	
16-55/ C459100 1 1226 12262080	3^	GENRL	Fatigue/ fatigue	1	07OCT2020	3/3	2	Yes		NA	R (09OCT2020)	N/N	
		MUSC	Myalgia/ muscle pain	1	07OCT2020	3/3	2	Yes		NA	R (09OCT2020)	N/N	
		NERV	Headache/ headache	1	07OCT2020	3/3	2	Yes		NA	R (09OCT2020)	N/N	
16-55/ C459100 1 1226 12262081	3^	GENRL	Injection site pain/ Pain at the injection site	1	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N	
		GENRL	Injection site pain/ Pain at injection site	2	27OCT2020	1/C	1	Yes		NA	RG	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12262085	3^	GENRL	Injection site pain/ injection site pain	1	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1226 12262086	3^	GENRL	Injection site pain/ Pain at injection site	1	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1226 12262089	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	18OCT2020	13/5	3	No	O	NA/TC	R (22OCT2020)	Y/N
16-55/ C459100 1 1226 12262095	3^	GENRL	Injection site pain/ Pain at injection site	1	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
		GENRL	Pyrexia/ Fever	1	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
		NERV	Headache/ Headache	1	08OCT2020	3/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1226 12262099	3^	MUSC	Arthralgia/ Joint pain in elbows	1	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1226 12262104	3^	GENRL	Injection site pain/ pain at injection site	1	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
			Pyrexia/ fever (38 C)	1	08OCT2020	2/1	2	Yes		NA	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N
		GENRL	Chills/ Chills	2	30OCT2020	3/1	1	Yes		NA	R (30OCT2020)	N/N
		MUSC	Costochondritis/ Costochondritis in the sternal region	2	30OCT2020	3/C	3	No	O	NA	RG	N/N
16-55/ C459100 1 1226 12262105	3^	NERV	Headache/ Headache	1	15OCT2020	9/4	1	No	O	NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 1226 12262107	3^	GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux disease	1	16OCT2020	9/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1226 12262110	3^	GENRL	Injection site pain/ Pain at the injection site	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ Headache	1	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1226 12262112	3^	GENRL	Pyrexia/ fever	1	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		INJ&P	Wound/ piercing-sharp accident	1	17OCT2020	10/2	1	No	O	NA/TC	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12262113	3^	GENRL	Injection site pain/ Pain at the injection site	1	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		INV	Body temperature increased/ Body temperature elevated 37.3 C	1	09OCT2020	2/2	2	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1226 12262115	3^	GENRL	Injection site pain/ Pain at injection site	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1226 12262117	3^	MUSC	Myalgia/ muscle pain	1	10OCT2020	2/5	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1226 12262120	3^	GENRL	Chills/ chills	1	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1226 12262121	3^	INFEC	Cystitis/ cystitis	1	20OCT2020	12/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1226 12262126	3^	GASTR	Diarrhoea/ Diarrhea	1	09OCT2020	1/1	1	Yes		NA/TC	R (09OCT2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	1	09OCT2020	1/5	2	Yes		NA/TC	R (13OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12262127	3^	GENRL	Pyrexia/ Fever 39.6 C	1	10OCT2020	2/1	3	Yes		NA/TC	R (10OCT2020)	N/N
		MUSC	Arthralgia/ Joint pain	1	10OCT2020	2/4	1	Yes		NA	R (13OCT2020)	N/N
			Myalgia/ Muscle pain	1	10OCT2020	2/4	1	Yes		NA	R (13OCT2020)	N/N
		NERV	Headache/ Headache	1	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
		REPRO	Pelvic pain/ Pelvic pain	1	13OCT2020	5/3	2	No	O	NA/TC	R (15OCT2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12262137	3^	GENRL	Injection site pain/ Pain at the injection site	1	09OCT2020	1/3	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C459100 1 1226 12262138	3^	MUSC	Myalgia/ Muscle pain	1	11OCT2020	3/2	1	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C459100 1 1229 12291012	3^	MUSC	Myalgia/ localised non specific myalgia	2	19OCT2020	5/9	1	No	CND	NA	R (27OCT2020)	N/N
16-55/ C459100 1 1229 12291031	3^	NERV	Headache/ Headache	1	28SEP2020	1/24	1	No	O	NA	R (21OCT2020)	N/N
16-55/ C459100 1 1229 12291145	3^	INFEC	Upper respiratory tract infection/ Upper Respiratory Tract Infection	2	13NOV2020	16/C	1	No	O	NA/TC	N	N/N
		RESP	Nasal turbinate hypertrophy/ Swollen Turbinates	2	13NOV2020	16/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1230 12301001	3^	SKIN	Erythema/ Erythema medial aspect on Humerus Left upper extremity (not by injection site)	1	23SEP2020	1/7	2	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C459100 1 1230 12301011	3^	INJ&P	Ankle fracture/ Broken Ankle	1	12OCT2020	20/C	1	No	O	NA/TC/TCN	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1230 12301045	3 [†]	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	1	20OCT2020	22/C		No	O	P	UNK	N/N
16-55/ C459100 1 1230 12301129	3 [^]	GENRL	Fatigue/ Moderate Fatigue	1	08OCT2020	4/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		NERV	Headache/ Severe Headache	1	08OCT2020	4/2	3	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1230 12301134	3 [^]	INJ&P	Thermal burn/ Burn Wound on Left forearm	1	23OCT2020	19/C	2	No	O	NA/TCN	RG	N/N
16-55/ C459100 1 1230 12301214	3 [^]	MUSC	Myalgia/ Generalized Muscle Pain	2	31OCT2020	2/3	3	Yes		NA/TC	R (02NOV2020)	N/N
16-55/ C459100 1 1231 12311001	3 [^]	SKIN	Rash/ abdomen skin rash	2	17SEP2020	22/4	1	No	O	NA	R (20SEP2020)	N/N
			Rash/ back skin rash	2	17SEP2020	22/4	1	No	O	NA	R (20SEP2020)	N/N
			Rash/ both arms skin rash	2	17SEP2020	22/4	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C459100 1 1231 12311003	3 [^]	MUSC	Back pain/ mild low back pain	2	18SEP2020	23/14	1	No	O	NA/TC	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12311008	3^	NERV	Headache/ Headache	2	19SEP2020	24/1	1	No	O	NA	R (19SEP2020)	N/N
16-55/ C459100 1 1231 12311027	3^	NERV	Sciatica/ chronic lumbociatalgia exacerbated	1	25AUG2020	16/12	2	No	O	NA/TC	R (05SEP2020)	N/N
		INFEC	Soft tissue infection/ Right elbow soft tissue infection	1	03SEP2020	25/12	1	No	O	NA/TC	R (14SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN IN BOTH UPPER LIMBS	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1231 12311036	3^	INFEC	Tooth infection/ Upper molar infection	2	09SEP2020	8/8	1	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1231 12311043	3^	PSYCH	Anxiety disorder/ Anxiety Disorder	2	26SEP2020	26/1	2	No	O	NA	R (26SEP2020)	N/N
		INJ&P	Heat stroke/ insolation	2	01NOV2020	62/2	1	No	O	NA/TC	R (02NOV2020)	N/N
16-55/ C459100 1 1231 12311051	3^	VASC	Hypertension/ high blood pressure	2	24SEP2020	24/1	1	No	O	NA/TC	R (24SEP2020)	N/N
16-55/ C459100	3^	INFEC	Tooth infection/ odontogenic infection	2	03SEP2020	3/29	2	No	O	NA/TCN	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12311052		MUSC	Back pain/ low back pain	2	24OCT2020	54/7	1	No	O	NA	R (30OCT2020)	N/N
16-55/ C459100 1 1231 12311058	3^	EAR	Deafness unilateral/ hearing loss in the left ear	2	27SEP2020	27/12	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C459100 1 1231 12311065	3^	MUSC	Myalgia/ Myalgia	2	20OCT2020	50/2	1	No	O	NA/TC	R (21OCT2020)	N/N
16-55/ C459100 1 1231 12311074	3^	EAR	Tinnitus/ exacerbation of bilateral tinnitus.	1	30AUG2020	19/31	2	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C459100 1 1231 12311077	3^	INJ&P	Tooth fracture/ BROKEN SECOND MOLAR	2	28SEP2020	28/1	1	No	O	NA/TC	R (28SEP2020)	N/N
		SURG	Dental care/ DENTAL TREATMENT	2	28SEP2020	28/1	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N
16-55/ C459100 1 1231 12311085	3^	MUSC	Tenosynovitis stenosaurs/ De Quervain's tenosynovitis	1	17AUG2020	6/64	2	No	O	NA/TC/TCN	R (19OCT2020)	N/N
16-55/ C459100	3^	EYE	Chalazion/ Chalazion	2	03OCT2020	33/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12311095	3^	GASTR	Diarrhoea/ Diarrhea	1	23AUG2020	12/3	1	No	O	NA	R (25AUG2020)	N/N
1 1231 12311097		GASTR	Diarrhoea/ Diarrhea	2	09SEP2020	8/1	1	No	O	NA/TCN	R (09SEP2020)	N/N
16-55/ C459100	3^	GASTR	Dyspepsia/ dyspepsia	2	20SEP2020	19/9	1	No	O	NA	R (28SEP2020)	N/N
1 1231 12311105	3^	VASC	Phlebitis superficial/ Superficial phlebitis of the left arm	2	11OCT2020	38/19	2	No	O	NA/TC	R (29OCT2020)	N/N
16-55/ C459100	3^	MUSC	Myalgia/ Myalgia	1	19AUG2020	7/11	1	No	O	NA	R (29AUG2020)	N/N
1 1231 12311121	3^	INJ&P	Joint dislocation/ right shoulder dislocation	2	22SEP2020	22/1	3	No	O	NA/TC/TCN	RS (22SEP2020)	N/N
16-55/ C459100			Road traffic accident/ MOTOR VEHICLE ACCIDENT	2	22SEP2020	22/1	3	No	O	NA/TC/TCN	RS (22SEP2020)	N/N
1 1231 12311126	3^	NERV	Headache/ headache	2	13SEP2020	11/3	1	No	O	NA/TC	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12311130	3^	INFE	Genital herpes/ exacerbated genital herpes	2	27SEP2020	26/9	1	No	O	NA/TC/TCN	R (05OCT2020)	N/N
1 1231 12311141	3^	MUSC	Arthralgia/ Joint pain	2	10SEP2020	7/36	2	No	O	NA/TC	R (15OCT2020)	N/N
1 1231 12311152		MUSC	Arthralgia/ pain in right knee	2	07OCT2020	34/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1231 12311164	3^	GASTR	Abdominal pain/ Abdominal pain	2	02SEP2020	1/2	3	No	O	NA/TC/TCN	R (03SEP2020)	N/N
16-55/ C459100 1 1231 12311166	3^	SKIN	Dermatitis bullous/ bullous lesion on right hand	2	30SEP2020	28/31	1	No	O	NA/TC	R (30OCT2020)	N/N
		MUSC	Arthralgia/ Left shoulder arthralgia	2	20OCT2020	48/8	1	No	O	NA/TC	R (27OCT2020)	N/N
16-55/ C459100 1 1231 12311176	3^	INFE	Tooth infection/ Dental infection	2	08SEP2020	5/7	1	No	O	NA/TC	R (14SEP2020)	N/N
		INJ&P	Tooth fracture/ Tooth fracture	2	08SEP2020	5/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INFEC	Oral herpes/ Cold sores	2	31OCT2020	58/3	1	No	O	NA	R (02NOV2020)	N/N
16-55/ C459100 1 1231 12311183	3^	GASTR	Toothache/ Toothache	2	27SEP2020	26/4	2	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1231 12311191	3^	INFEC	Cystitis/ Cystitis	1	09OCT2020	57/3	1	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C459100 1 1231 12311195	3^	INFEC	Conjunctivitis/ Conjunctivitis	1	20AUG2020	7/2	1	No	O	NA/TC	R (21AUG2020)	N/N
16-55/ C459100 1 1231 12311199	3^	INFEC	Genital herpes simplex/ Genital herpes simplex type 2	2	16SEP2020	14/13	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C459100 1 1231 12311205	3^	INJ&P	Ulna fracture/ Left arm olecranon fracture	2	17SEP2020	15/C	3	No	O	NA/TC/TCN	RG	Y/N
16-55/ C459100 1 1231 12311211	3^	INJ&P	Fall/ Fall from his own height	1	19SEP2020	37/1	2	No	O	NA	R (19SEP2020)	N/N
		MUSC	Coccydynia/ Coccigodinia	1	19SEP2020	37/22	2	No	O	NA/TC/TCN	R (10OCT2020)	N/N
16-55/ C459100	3^	CARD	Tachycardia/ tachycardia	2	06OCT2020	33/C	2	No	O	NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12311229	3^	IN FEC	Tooth infection/ dental infection	1	24AUG2020	11/7	2	No	O	NA/TC	R (30AUG2020)	N/N
1 1231 12311231	3^	VASC	Hypertension/ exacerbation of arterial hypertension	2	15SEP2020	14/3	1	No	O	NA/TC/TCN	R (17SEP2020)	N/N
1 1231 12311233	3^	GASTR	Odynophagia/ Odynophagia	2	16SEP2020	15/4	1	No	O	NA	R (19SEP2020)	N/N
1 1231 12311238		GENRL	Asthenia/ asthenia	2	16SEP2020	15/2	1	No	O	NA	R (17SEP2020)	N/N
16-55/ C459100 1 1231 12311243	3^	SKIN	Rash pruritic/ pruritic rash	1	18AUG2020	5/4	2	Yes		NA/TC	R (21AUG2020)	N/N
16-55/ C459100 1 1231 12311248	3^	EYE	Blepharitis/ Left blepharitis	2	30SEP2020	27/10	1	No	O	NA/TC	R (09OCT2020)	N/N
			Eyelid pain/ PAIN OF THE UPPER LEFT EYELID	2	30SEP2020	27/10	1	No	O	NA/TC	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12311281	3^	INFEC	Eyelids pruritus/ ITCHING OF THE UPPER LEFT EYELID	2	30SEP2020	27/10	1	No	O	NA/TC	R (09OCT2020)	N/N
			Appendicitis/ acute appendicitis	2	18SEP2020	15/19	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N
			Electrocardiogram QT prolonged/ QT interval prolongation	2	18SEP2020	15/1	1	No	O	NA	R (18SEP2020)	N/N
16-55/ C459100 1 1231 12311294	3^	INFEC	Pyelonephritis/ pyelonephritis	2	12SEP2020	6/9	3	No	O	NA/TC	R (20SEP2020)	N/N
			INJ&P	Bone fissure/ Fissure of left elbow bone	2	23OCT2020	47/C	1	No	O	NA/TC/TCN	N
16-55/ C459100 1 1231 12311295	3^	BLOOD		Joint dislocation/ Dislocation of the left elbow	2	23OCT2020	47/C	1	No	O	NA/TC/TCN	N
			Lymphadenopathy/ Left axillary adenopathy	2	05SEP2020	3/16	1	Yes		NA/TC/TCN	R (20SEP2020)	N/N
			NERV	Tension headache/ Tension headache	2	05OCT2020	33/11	2	No	O	NA/TC	R (15OCT2020)
16-55/ C459100 1 1231 12311301	3^	RESP	Asthma/ Moderate asthma attack	1	26AUG2020	12/5	2	No	O	NA/TC	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12311306	3^	GENRL	Chest pain/ Self-limited oppressive chest pain	1	02SEP2020	19/1	1	No	O	NA	R (02SEP2020)	N/N
16-55/ C459100 1 1231 12311315	3^	BLOOD	Anaemia/ anemia	2	25SEP2020	23/C	2	No	O	NA/TC	RG	N/N
		NEOPL	Malignant melanoma/ Pigmented epithelioid melanoma of the vagina	2	25SEP2020	23/C	2	No	O	NA/TC/TCN	N	Y/N
16-55/ C459100 1 1231 12311336	3^	INJ&P	Procedural dizziness/ Post blood extraction dizziness	2	07OCT2020	35/1	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C459100 1 1231 12311338	3^	GASTR	Gastrointestinal disorder/ Gastrointestinal syndrome	2	09SEP2020	3/2	2	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1231 12311348	3^	GENRL	Injection site pain/ local pain at the injection site*		15AUG2020	1/1	1	Yes		NA/TC	R (15AUG2020)	N/N
16-55/ C459100 1 1231 12311352	3^	GENRL	Influenza like illness/ Flu like syndrome	1	20AUG2020	6/3	3	No	O	NA	R (22AUG2020)	Y/N
		INFEC	Urinary tract infection/ high urinary infection	1	20AUG2020	6/71	2	No	O	NA/TC	R (29OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12311361	3^	GASTR	Vomiting/ Vomiting	1	29AUG2020	15/4	1	No	O	NA	R (01SEP2020)	N/N
		NERV	Paraesthesia/ Both upper limbs paresthesia	2	04SEP2020	1/1	1	No	O	NA	R (04SEP2020)	N/N
16-55/ C459100 1 1231 12311375	3^	PSYCH	Generalised anxiety disorder/ generalized anxiety	2	07OCT2020	34/C	1	No	O	NA/TC/TCN	N	N/N
		MUSC	Arthralgia/ Polyarthralgias	2	12OCT2020	39/C	1	No	O	NA	N	N/N
		MUSC	Myalgia/ Myalgia in the region of the shoulder and left shoulder blade	2	06SEP2020	4/1	2	Yes		NA/TC	R (06SEP2020)	N/N
16-55/ C459100 1 1231 12311388	3^	MUSC	Myalgia/ Myalgia of moderate intensity below the left shoulder blade	2	26SEP2020	24/1	2	No	O	NA/TC	R (26SEP2020)	N/N
		NERV	Headache/ headache	1	16AUG2020	2/8	1	No	O	NA	R (23AUG2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	1	18AUG2020	4/7	1	Yes		NA	R (24AUG2020)	N/N
		MUSC	Arthralgia/ ARTHRALGIA	1	21AUG2020	7/4	1	No	O	NA	R (24AUG2020)	N/N
		SURG	Tooth extraction/ Programmed extraction of the right third molar	2	26SEP2020	24/1	1	No	CND	NA/TC/TCN	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12311402	3^	NERV	Headache/ worsening headache	1	08OCT2020	55/2	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C459100 1 1231 12311403	3^	MUSC	Synovial cyst/ Right wrist ganglion	2	04NOV2020	60/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1231 12311409	3^	GASTR	Vomiting/ vomits*		15AUG2020	/1	1	No	O	P/TCN/W	R (15AUG2020)	N/N
		NERV	Syncope/ Syncope*		15AUG2020	/1	2	No	O	P/TCN/W	R (15AUG2020)	N/N
16-55/ C459100 1 1231 12311410	3^	REPRO	Amenorrhoea/ Amenorrhea	2	16SEP2020	11/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1231 12311412	3^	MUSC	Musculoskeletal chest pain/ Torax pain. refered muscular. type oppressive.	2	15SEP2020	1/52	2	No	O	NA	R (05NOV2020)	N/N
16-55/ C459100 1 1231 12311414	3^	INFEC	Urinary tract infection/ urinary infection	1	30AUG2020	16/8	1	No	O	NA/TC	R (06SEP2020)	N/N
16-55/ C459100 1 1231 12311418	3^	GASTR	Inguinal hernia/ bilateral inguinal hernia	1	27AUG2020	13/2	2	No	O	NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Irritable bowel syndrome/ irritable bowel syndrome	1	27AUG2020	13/C	2	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 1 1231 12311427	3^	RESP	Bronchospasm/ Bronchospasm	2	08SEP2020	6/39	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1231 12311428	3^	GENRL	Pyrexia/ fever	2	18SEP2020	12/1	1	No	O	NA	R (18SEP2020)	N/N
16-55/ C459100 1 1231 12311436	3^	GASTR	Diarrhoea/ diarrhea	2	30SEP2020	28/2	1	No	O	NA/TCN	R (01OCT2020)	N/N
16-55/ C459100 1 1231 12311444	3^	SKIN	Dermatitis contact/ contact dermatitis	1	19AUG2020	5/53	1	No	O	NA	R (10OCT2020)	N/N
			Rash maculo-papular/ non pruritic maculopapular cervical rash	1	19AUG2020	5/53	1	No	O	NA	R (10OCT2020)	N/N
16-55/ C459100 1 1231 12311465	3^	RESP	Bronchospasm/ MILD BRONCHOSPASM	2	30SEP2020	28/2	1	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1231 12311473	3^	MUSC	Back pain/ low back pain	1	20AUG2020	6/2	1	No	O	NA/TC	R (21AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12311475	3^	GASTR	Diarrhoea/ diarrhea	1	22AUG2020	8/2	1	No	O	NA	R (23AUG2020)	N/N
16-55/ C459100 1 1231 12311480	3^	SKIN	Rash/ skin rash, left laterocervical region	2	27SEP2020	25/14	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1231 12311483	3^	RESP	Rhinitis allergic/ allergic rhinitis	2	30SEP2020	28/1	1	No	O	NA/TC	RS (30SEP2020)	N/N
16-55/ C459100 1 1231 12311492	3^	REPRO	Penile vein thrombosis/ Thrombosis of superficial vein of penis	2	14SEP2020	8/27	1	No	O	NA/TC	R (10OCT2020)	N/N
		INJ&P	Post procedural haemorrhage/ Bleeding after sampling	2	07OCT2020	31/1	1	No	O	NA/TCN	R (07OCT2020)	N/N
16-55/ C459100 1 1231 12311499	3^	MUSC	Myalgia/ myalgia in lower limbs	1	10SEP2020	26/C	1	No	O	NA/TC	RG	N/N
		SKIN	Pruritus/ generalized itching	2	21SEP2020	1/C	2	Yes		NA/TC/TCN	N	N/N
		NERV	Headache/ headache	2	03OCT2020	13/C	2	No	O	NA/TC/TCN	N	N/N
		GENRL	Chills/ Chills	2	20OCT2020	30/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	20OCT2020	30/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1231 12311507	3^	INFEC	Vulvovaginal mycotic infection/ Vaginal mycosis	2	17SEP2020	11/3	1	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1231 12311513	3^	SURG	Tooth extraction/ Elective extraction of three third molars	2	03OCT2020	26/1	1	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1231 12311520	3^	INFEC	Folliculitis/ Folliculitis in upper dorsal area and nape.	2	07NOV2020	62/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1231 12311530	3^	PSYCH	Anxiety disorder/ Anxiety disorder	2	26OCT2020	49/3	2	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C459100 1 1231 12311532	3^	VASC	Hypertension/ arterial hypertension	1	27AUG2020	12/4	1	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C459100 1 1231 12311544	3^	GENRL	Chills/ chills	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
			Injection site erythema/ Erythema at the injection site	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
			Injection site pain/ Injection site pain	2	04SEP2020	1/2	1	Yes		NA/TC	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12311548	3^	EYE	Eyelid oedema/ unilateral bipalpebral edema	2	09SEP2020	2/34	1	No	O	NA	R (12OCT2020)	N/N
		SKIN	Pruritus/ Pruritus of the face and neck	2	09SEP2020	2/34	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C459100 1 1231 12311556	3^	GENRL	Asthenia/ Asthenia	2	23SEP2020	17/1	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C459100 1 1231 12311584	3^	INFEC	Conjunctivitis/ Conjunctivitis	2	16SEP2020	9/8	1	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1231 12311607	3^	MUSC	Muscle contracture/ Left deltoid muscle contracture	2	01OCT2020	24/2	1	No	O	NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1231 12311638	3^	MUSC	Neck pain/ Cervicalgia	2	04OCT2020	27/C	1	No	O	NA/TC	N	N/N
		MUSC	Spinal deformity/ Cervical Spine curvature	2	10OCT2020	33/C	2	No	O	NA/TC	RG	N/N
		PSYCH	Anxiety disorder/ Anxiety disorder	2	12OCT2020	35/29	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N
			Depression/ Depression	2	12OCT2020	35/C	2	No	O	NA/TC/TCN	RG	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12311643	3^	GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux	1	25AUG2020	10/6	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C459100 1 1231 12311651	3^	NERV	Dizziness/ Lipothymia Dizziness	1	17AUG2020	2/3	1	No	O	NA/TC/TCN	R (19AUG2020)	N/N
16-55/ C459100 1 1231 12311653	3^	CARD	Palpitations/ worsening heart palpitations	2	SEP2020	1/	1	No	O	NA	R (16OCT2020)	N/N
		GENRL	Pyrexia/ Fever	2	08SEP2020	2/1	3	Yes		NA/TC	R (08SEP2020)	N/N
		METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	28SEP2020	22/19	1	No	O	NA/TC	R (16OCT2020)	N/N
			Hypocalcaemia/ Hypocalcemia	2	28SEP2020	22/19	1	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1231 12311660	3^	RESP	Dyspnoea/ Dyspnea	1	22AUG2020	7/2	1	No	O	NA	R (23AUG2020)	N/N
16-55/ C459100 1 1231 12311661	3^	GENRL	Injection site pain/ pain at the injection site	2	27SEP2020	21/10	1	Yes		NA	R (06OCT2020)	N/N
		GENRL	Peripheral swelling/ swelling in the left arm	2	29SEP2020	23/8	1	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INJ&P	Contusion/ bruise in the left arm	2	29SEP2020	23/8	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1231 12311683	3^	GENRL	Pyrexia/ fever	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1231 12311686	3^	GASTR	Haemorrhoids/ hemorrhoids	2	21SEP2020	14/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1231 12311689	3^	GENRL	Oedema peripheral/ Left ankle Edema	1	01SEP2020	16/63	1	No	O	NA	R (02NOV2020)	N/N
		MUSC	Arthralgia/ pain in the left ankle	1	01SEP2020	16/63	1	No	O	NA	R (02NOV2020)	N/N
16-55/ C459100 1 1231 12311701	3^	GASTR	Dyspepsia/ Dyspepsia	1	17AUG2020	1/8	3	Yes		NA/TC/TCN	R (24AUG2020)	N/N
16-55/ C459100 1 1231 12311711	3^	INFEC	Urosepsis/ Urosepsis	2	15SEP2020	9/8	3	No	O	NA/TC	R (22SEP2020)	Y/N
16-55/ C459100 1 1231 12311712	3^	INFEC	Tooth infection/ Odontogenic infection	2	23SEP2020	16/1	1	No	O	NA/TCN	R (23SEP2020)	N/N
16-55/ C459100	3^	REPRO	Genital erythema/ Nonspecific glans erythema	2	24SEP2020	18/2	1	No	O	NA/TC	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12311714	3^	NERV	Headache/ headache	2	07SEP2020	1/3	2	Yes		NA/TC	R (09SEP2020)	N/N
1 1231 12311719	3^	INFEC	Rhinitis/ rhinitis	1	19AUG2020	3/8	1	No	O	NA	R (26AUG2020)	N/N
1 1231 12311724		RESP	Rhinitis allergic/ allergic rhinitis	2	02OCT2020	26/2	1	No	O	NA	R (03OCT2020)	N/N
16-55/ C459100 1 1231 12311731	3^	NERV	Headache/ HEADACHE	1	05SEP2020	20/2	2	No	O	NA/TC/TCN	R (06SEP2020)	N/N
		NERV	Headache/ headache	2	03OCT2020	26/1	2	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1231 12311734	3^	GASTR	Dyspepsia/ Dyspepsia	2	22OCT2020	46/3	1	No	O	NA	R (24OCT2020)	N/N
16-55/ C459100 1 1231 12311740	3^	EAR	Tinnitus/ ringing in both ears	2	08SEP2020	2/C	3	No	O	NA	N	N/N
16-55/ C459100	3^	EAR	Vertigo/ Vertigo	2	01OCT2020	25/8	2	No	O	NA	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12311746	3^	SKIN	Pruritus allergic/ allergic reaction producing pruritus at the chin	1	22AUG2020	6/2	1	Yes		NA	R (23AUG2020)	N/N
1 1231 12311755		SKIN	Rash pruritic/ pruritic rash on arm, armpit and part of the left chest.	2	13SEP2020	7/4	1	No	O	NA/TC	R (16SEP2020)	N/N
		INJ&P	Limb injury/ Stabbing trauma on right thumb	2	08OCT2020	32/C	1	No	O	NA/TC	RG	N/N
		INFEC	Cellulitis/ cellulitis of the righth thumb	2	10OCT2020	34/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 1 1231 12311760	3^	SKIN	Pruritus/ pruritus upper region of both feet and palmar aspect of both wrists	1	24AUG2020	8/2	1	No	O	NA	R (25AUG2020)	N/N
16-55/ C459100 1 1231 12311763	3^	GENRL	Injection site pain/ injection site pain	2	08SEP2020	2/14	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1231 12311766	3^	HEPAT	Biliary colic/ biliary colic	2	30OCT2020	54/5	3	No	O	NA/TC	R (03NOV2020)	Y/N
16-55/ C459100 1 1231 12311769	3^	NERV	Dizziness/ dizziness	1	18AUG2020	2/11	1	No	O	NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12311770	3^	GASTR	Diarrhoea/ diarrhea	2	14SEP2020	8/3	1	No	O	NA	R (16SEP2020)	N/N
		NERV	Headache/ headache	2	14SEP2020	8/3	1	No	O	NA	R (16SEP2020)	N/N
		GASTR	Odynophagia/ odynophagia	2	17SEP2020	11/4	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C459100 1 1231 12311780	3^	UNC	GASTROESOPHAGEAL REFLUX@@/ Gastroesophageal reflux	1	28AUG2020	12/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1231 12311786	3^	INJ&P	Fall/ Subject fell down on the street	2	23SEP2020	17/1	1	No	O	NA	R (23SEP2020)	N/N
		NEOPL	Chondroma/ Right knee chondroma	2	29SEP2020	23/C	1	No	O	NA	N	N/N
		RESP	Asthmatic crisis/ Asthmatic crisis	2	04OCT2020	28/4	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1231 12311788	3^	PSYCH	Depression/ depression.	1	20AUG2020	4/36	2	No	O	NA/TC/TCN	R (24SEP2020)	N/N
16-55/ C459100 1 1231 12311793	3^	MUSC	Back pain/ Low back pain	1	05SEP2020	20/2	1	No	O	NA/TC	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12311794	3^	METAB	Insulin resistance/ Worsening of the insuline resistance.	2	20SEP2020	14/19	2	No	O	NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1231 12311797	3^	VASC	Hypertension/ arterial hypertension	2	25SEP2020	19/8	1	No	O	NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1231 12311801	3^	MUSC	Muscle contracture/ Left back, muscle contracture	1	29AUG2020	13/4	2	No	O	NA/TC/TCN	R (01SEP2020)	N/N
16-55/ C459100 1 1231 12311811	3^	SKIN	Pityriasis/ Pityriasis	1	25AUG2020	9/51	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C459100 1 1231 12311825	3^	NERV	Migraine/ Migraine crysis	1	05SEP2020	20/1	2	No	O	NA	R (05SEP2020)	N/N
		NERV	Migraine/ Migraine crisis	2	08NOV2020	35/2	1	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C459100 1 1231 12311827	3^	MUSC	Osteoarthritis/ Right acromioclavicular osteoarthritis	2	17SEP2020	10/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C459100 1 1231 12311834	3^	INJ&P	Foot fracture/ Hallux fracture and second toe of the right foot	2	16SEP2020	10/35	3	No	O	NA/TC/TCN	R (20OCT2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12311836	3^	INFEC	Herpes simplex/ herpes simplex type 1 in the right nasal wing	1	19AUG2020	3/4	1	No	O	NA/TC	R (22AUG2020)	N/N
		INFEC	Herpes simplex/ herpes simplex type 1 on the left wing of the nose	2	10SEP2020	3/3	1	No	O	NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1231 12311837	3^	PSYCH	Anxiety/ anxiety crisis	2	03OCT2020	27/2	2	No	O	NA/TC/TCN	R (04OCT2020)	N/N
		INFEC	Oral herpes/ Herpes labialis, single lesion	2	20OCT2020	44/8	1	No	O	NA	R (27OCT2020)	N/N
		INFEC	Syphilis/ Syphilis	2	27OCT2020	51/C	2	No	O	NA/TC/TCN	N	N/N
		IMMUN	Jarisch-Herxheimer reaction/ Jarisch-herxheimer	2	13NOV2020	68/2	2	No	O	NA/TC	R (14NOV2020)	N/N
16-55/ C459100 1 1231 12311844	3^	METAB	Hypoglycaemia/ severe hipoglycemia	2	16OCT2020	40/1	3	No	O	NA	R (16OCT2020)	Y/N
		NERV	Seizure/ seizure	2	16OCT2020	40/1	3	No	O	NA	R (16OCT2020)	N/N
16-55/ C459100 1 1231 12311850	3^	SKIN	Rash/ Skin Rash on legs, arms and back	1	25AUG2020	9/2	1	No	O	NA/TC	R (26AUG2020)	N/N
16-55/ C459100	3^	EYE	Episcleritis/ bilateral episcleritis	1	04SEP2020	19/19	1	No	O	NA/TC	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12311863	3^	BLOOD	Lymphadenopathy/ right axillary adenopathy	2	10SEP2020	3/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1231 12311865	3^	INFEC	Urinary tract infection/ urinary infection	2	29SEP2020	22/5	1	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1231 12311885	3^	NERV	Migraine/ Worsening migraine	1	25AUG2020	8/14	1	No	O	NA/TC	R (07SEP2020)	N/N
16-55/ C459100 1 1231 12311888	3^	SKIN	Rash pruritic/ Pruritic rash in abdomen.	2	10SEP2020	3/3	1	No	O	NA/TCN	R (12SEP2020)	N/N
16-55/ C459100 1 1231 12311901	3^	NERV	Headache/ headache	2	04OCT2020	27/2	2	No	O	NA/TC	R (05OCT2020)	N/N
16-55/ C459100 1 1231 12311908	3^	GASTR	Odynophagia/ odynophagia	2	09SEP2020	2/5	2	No	O	NA	R (13SEP2020)	N/N
		NERV	Headache/ headache	2	09SEP2020	2/5	2	No	O	NA/TC	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12311926	3^	NERV	Syncope/ Syncope*		18AUG2020	/1	2	No	O	NA/W	R (18AUG2020)	N/N
16-55/ C459100 1 1231 12311951	3^	INFEC	Tooth infection/ Odontogenic infection	2	23SEP2020	15/23	1	No	O	NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1231 12311964	3^	INFEC	Tooth abscess/ Periodontogenic abscess	2	15SEP2020	9/8	1	No	O	NA/TC	R (22SEP2020)	N/N
16-55/ C459100 1 1231 12311969	3^	REPRO	Erectile dysfunction/ Erectile dysfunction*		18AUG2020	1/81	1	No	O	NA	R (06NOV2020)	N/N
		CARD	Tricuspid valve incompetence/ mild tricuspid regurgitation	2	03OCT2020	27/24	1	No	O	NA	R (26OCT2020)	N/N
16-55/ C459100 1 1231 12312002	3^	NERV	Headache/ headache	1	01SEP2020	15/1	3	No	O	NA	R (01SEP2020)	N/N
16-55/ C459100 1 1231 12312004	3^	PSYCH	Generalised anxiety disorder/ generalized anxiety disorder	2	15SEP2020	6/1	2	No	O	NA/TC	R (15SEP2020)	N/N
16-55/ C459100 1 1231 12312010	3^	INFEC	Gastroenteritis/ gastroenteritis	2	17SEP2020	10/7	1	No	O	NA/TC/TCN	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312019	3^	INJ&P	Contusion/ bruising on both upper limbs	2	30SEP2020	22/14	1	No	O	NA	R (13OCT2020)	N/N
16-55/ C459100 1 1231 12312024	3^	GASTR	Dyspepsia/ Pyrosis	2	27SEP2020	20/30	1	No	O	NA	R (26OCT2020)	N/N
			Salivary gland mucocoele/ Lower lip mucocoele	2	27SEP2020	20/C	1	No	O	NA	N	N/N
		MUSC	Pain in extremity/ Lower limbs pain	2	07OCT2020	30/2	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C459100 1 1231 12312029	3^	GASTR	Toothache/ odontogenic pain	1	27AUG2020	10/44	2	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1231 12312036	3^	GASTR	Abdominal pain/ abdominal pain	2	25SEP2020	17/7	1	No	O	NA/TC/TCN	R (01OCT2020)	N/N
		SKIN	Hand dermatitis/ dermatitis on both hands	2	08OCT2020	30/14	1	No	O	NA	R (21OCT2020)	N/N
16-55/ C459100 1 1231 12312037	3^	GASTR	Vomiting/ Threw up	2	09OCT2020	31/1	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C459100 1 1231 12312042	3^	NERV	Headache/ headache	2	18OCT2020	41/3	1	No	O	NA/TC	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312046	3^	INJ&P	Skin laceration/ Cutting wound on left hand	2	04OCT2020	28/6	1	No	O	NA/TC/TCN	R (09OCT2020)	N/N
16-55/ C459100 1 1231 12312048	3^	GASTR	Toothache/ Worsening of odontogenic pain	2	13OCT2020	37/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1231 12312056	3^	GASTR	Abdominal pain/ Abdominal pain	2	16OCT2020	33/4	2	No	O	NA	R (19OCT2020)	N/N
16-55/ C459100 1 1231 12312063	3^	GENRL	Pyrexia/ Fever	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C459100 1 1231 12312068	3^	INFEC	Herpes zoster/ Herpes zoster in left dorsal region	2	08NOV2020	63/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1231 12312075	3^	INFEC	Tooth infection/ Dental infection	2	02OCT2020	26/43	1	No	O	NA/TC	R (13NOV2020)	N/N
16-55/ C459100 1 1231 12312077	3^	IMMUN	Seasonal allergy/ seasonal rhinitis	2	08OCT2020	3/4	1	No	O	NA	R (11OCT2020)	N/N
		INFEC	Gingivitis/ gingivitis	2	16OCT2020	11/5	1	No	O	NA/TC	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312078	3^	NERV	Migraine/ Worsening of Migraine	1	25AUG2020	8/36	2	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C459100 1 1231 12312080	3^	BLOOD	Lymphadenopathy/ left inguinal adenopathy	2	20OCT2020	43/15	1	No	O	NA	R (03NOV2020)	N/N
16-55/ C459100 1 1231 12312118	3^	NEOPL	Uterine leiomyoma/ uterine myoma	2	16OCT2020	39/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1231 12312128	3^	INJ&P	Joint injury/ right knee trauma	2	20SEP2020	13/11	2	No	O	NA/TC	R (30SEP2020)	N/N
			Road traffic accident/ Vehicular accident	2	20SEP2020	13/1	2	No	O	NA	R (20SEP2020)	N/N
16-55/ C459100 1 1231 12312137	3^	GENRL	Pyrexia/ Febrile syndrome	2	10SEP2020	2/1	3	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1231 12312152	3^	INFEC	Urinary tract infection/ URINARY INFECTION	1	04SEP2020	18/11	1	No	O	NA/TC	R (14SEP2020)	N/N
16-55/ C459100 1 1231 12312160	3^	GASTR	Odynophagia/ Odynophagia	2	08SEP2020	2/2	1	No	O	NA/TC	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312168	3^	GENRL	Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1231 12312174	3^	GASTR	Dental caries/ dental caries	2	08NOV2020	61/2	1	No	O	NA/TC/TCN	R (09NOV2020)	N/N
16-55/ C459100 1 1231 12312191	3^	RESP	Rhinitis allergic/ Allergic rhinitis.	2	01OCT2020	22/2	1	No	O	NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1231 12312204	3^	EYE	Chalazion/ chalazion	2	11OCT2020	31/4	2	No	O	NA	R (14OCT2020)	N/N
16-55/ C459100 1 1231 12312205	3^	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	29SEP2020	23/C		No	O	NA	UNK	N/N
16-55/ C459100 1 1231 12312211	3^	GENRL	Injection site pain/ Injection site pain in right deltoid	2	12SEP2020	4/4	2	Yes		NA	R (15SEP2020)	N/N
		MUSC	Myalgia/ Generalized myalgia	2	12SEP2020	4/4	2	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312212	3^	SURG	Drug titration/ dose search to achieve euthyroidism	2	08OCT2020	29/1	1	No	O	NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1231 12312219	3^	NERV	Headache/ Headache	1	29AUG2020	11/2	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C459100 1 1231 12312227	3^	GASTR	Diarrhoea/ Diarrhea	2	12SEP2020	4/1	1	Yes		NA	R (12SEP2020)	N/N
		MUSC	Back pain/ Dorsalgia	2	30SEP2020	22/3	1	No	O	NA	R (02OCT2020)	N/N
			Neck pain/ Cervicalgia	2	30SEP2020	22/3	1	No	O	NA/TCN	R (02OCT2020)	N/N
16-55/ C459100 1 1231 12312236	3^	NERV	Headache/ Headache	1	19AUG2020	1/2	3	No	O	NA	R (20AUG2020)	N/N
		PSYCH	Anxiety/ anxiety crisis	2	14SEP2020	4/27	2	No	O	NA/TC	R (10OCT2020)	N/N
			Depression/ Depression	2	14SEP2020	4/27	2	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1231 12312242	3^	IMMU N	Seasonal allergy/ Exacerbation of usual seasonal allergic rhinitis	2	27SEP2020	19/2	1	No	O	NA/TC	R (28SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312244	3^	NERV	Headache/ Headache	1	25AUG2020	7/52	1	No	O	NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1231 12312268	3^	MUSC	Arthralgia/ Right shoulder arthralgias	2	27SEP2020	17/C	1	No	O	NA/TC	N	N/N
			Arthralgia/ bilateral hand arthralgias	2	27SEP2020	17/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1231 12312270	3^	INJ&P	Limb injury/ Wound on the right leg	2	18OCT2020	38/9	1	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C459100 1 1231 12312282	3^	MUSC	Muscle contracture/ muscle contracture in left quadiceps	2	29SEP2020	22/1	3	No	O	NA	R (29SEP2020)	N/N
16-55/ C459100 1 1231 12312286	3^	GASTR	Odynophagia/ Odynophagia	1	29AUG2020	11/2	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C459100 1 1231 12312287	3^	GASTR	Abdominal pain upper/ Mild and intermittent epigastric abdominal pain.	2	10SEP2020	2/28	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C459100 1 1231 12312296	3^	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	3/1	1	No	O	NA	R (21AUG2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312300	3^	MUSC	Back pain/ Back pain	2	05OCT2020	26/2	2	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1231 12312303	3^	MUSC	Arthralgia/ Left omalgia	1	19AUG2020	1/C	2	No	O	NA	N	N/N
16-55/ C459100 1 1231 12312317	3^	NERV	Headache/ Headache	2	09SEP2020	3/9	1	Yes		NA/TC/TCN	R (17SEP2020)	N/N
16-55/ C459100 1 1231 12312320	3^	EAR	Vertigo/ vertiginous syndrome	1	08SEP2020	21/14	2	No	O	NA/TC	R (21SEP2020)	N/N
		EAR	Vertigo/ vertiginous syndrome	1	20SEP2020	33/27	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1231 12312330	3^	NERV	Dizziness/ Dizziness	1	20AUG2020	2/16	2	No	O	NA/TC	R (04SEP2020)	N/N
16-55/ C459100 1 1231 12312333	3^	MUSC	Tenosynovitis stenosaurs/ exacerbation of Right hand pain secondary to previous Quervain's tenosynovitis	2	28SEP2020	22/2	2	No	O	NA/TC	R (29SEP2020)	N/N
		SURG	Medical device implantation/ Radiocarpal clamping	2	28SEP2020	22/2	2	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C459100	3^	RESP	Rhinitis allergic/ Exacerbation of allergic rhinitis	2	15SEP2020	9/4	1	No	O	NA/TC	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12312346	3^	NERV	Paraesthesia/ left upper limb paresthesia	2	15SEP2020	5/22	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C459100 1 1231 12312351	3^	GASTR	Acute abdomen/ Acute medical abdomen	2	22SEP2020	14/4	2	No	O	NA	R (25SEP2020)	N/N
16-55/ C459100 1 1231 12312360	3^	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	1	05OCT2020	48/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1231 12312372	3^	NERV	Headache/ headache	1	21AUG2020	3/C	2	No	O	NA	N	N/N
		EAR	Meniere's disease/ Worsening of Meniere's Syndrome	1	24SEP2020	37/15	2	No	O	NA/TC/TCN	R (08OCT2020)	N/N
		PSYCH	Mental disorder/ Worsening of psychiatric disorder	2	15OCT2020	7/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 1 1231 12312373	3^	INFECTION	Skin infection/ scar infection	2	14OCT2020	30/9	1	No	O	NA/TC	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312382	3^	GENRL	Pyrexia/ fever (39 C)	2	09SEP2020	2/5	2	Yes		NA/TC	R (13SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	09SEP2020	2/5	2	Yes		NA/TC	R (13SEP2020)	N/N
		NERV	Headache/ Headache	2	09SEP2020	2/5	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100 1 1231 12312384	3^	METAB	Dyslipidaemia/ worsening dyslipidemia	2	20SEP2020	13/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1231 12312390	3^	MUSC	Osteochondritis/ Osteochondritis	1	05SEP2020	18/2	2	No	O	NA	R (06SEP2020)	Y/N
16-55/ C459100 1 1231 12312391	3^	GENRL	Pyrexia/ FEVER	2	11SEP2020	3/1	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1231 12312405	3^	SURG	Dental implantation/ Dental implant	2	19SEP2020	13/1	1	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1231 12312414	3^	GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux	1	25AUG2020	7/15	2	No	O	NA/TC/TCN	R (08SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	2	10SEP2020	2/1	3	Yes		NA/TC	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Relative ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12312419			Pyrexia/ fever	2	10SEP2020	2/1	3	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1231 12312424	3^	GENRL	Illness/ Sickness	2	11NOV2020	65/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1231 12312426	3^	MUSC	Back pain/ Low back pain	1	31AUG2020	13/4	2	No	O	NA/TC/TCN	R (03SEP2020)	N/N
16-55/ C459100 1 1231 12312434	3^	NERV	Dizziness/ dizziness	2	10SEP2020	2/16	1	No	O	NA/TCN	R (25SEP2020)	N/N
16-55/ C459100 1 1231 12312435	3^	MUSC	Back pain/ Acute low back pain	1	08SEP2020	21/3	1	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1231 12312439	3^	MUSC	Back pain/ acute low back pain	1	31AUG2020	13/11	1	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1231 12312444	3^	MUSC	Myalgia/ muscle pain in left arm	1	21AUG2020	2/2	3	Yes		NA/TCN	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312464	3^	NERV	Paraesthesia/ Upper limb paresthesias	2	17SEP2020	8/C	1	No	O	NA	N	N/N
		NERV	Headache/ Chronic headache	2	15OCT2020	36/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1231 12312477	3^	RESP	Rhinitis allergic/ worsening of allergic rhinitis	1	26AUG2020	7/1	1	No	O	NA	R (26AUG2020)	N/N
16-55/ C459100 1 1231 12312488	3^	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	2	03OCT2020	23/4	2	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1231 12312531	3^	INFEC	Tooth infection/ dental infection	2	16SEP2020	4/10	1	No	O	NA/TC/TCN	R (25SEP2020)	N/N
16-55/ C459100 1 1231 12312532	3^	INFEC	Gingivitis/ gingivitis	2	29SEP2020	19/8	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C459100 1 1231 12312533	3^	MUSC	Tendonitis/ exacerbation of tendonitis in the left wrist	2	30SEP2020	21/14	2	No	O	NA	R (13OCT2020)	N/N
16-55/ C459100 1 1231 12312538	3^	METAB	Vitamin D deficiency/ Hypovitaminosis D	2	16SEP2020	7/34	1	No	O	NA/TC	R (19OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312546	3^	NERV	Presyncope/ lipothymia (presyncope)	2	09OCT2020	29/1	2	No	O	NA	R (09OCT2020)	N/N
16-55/ C459100 1 1231 12312559	3^	NERV	Dizziness/ dizziness	1	23AUG2020	4/2	1	No	O	NA	R (24AUG2020)	N/N
16-55/ C459100 1 1231 12312576	3^	RENAL	Renal colic/ Renal colic	2	20OCT2020	42/1	2	No	O	NA/TC	R (20OCT2020)	N/N
		RENAL	Hydronephrosis/ Right hydronephrosis	2	05NOV2020	58/C	2	No	O	NA/TC	N	N/N
			Renal colic/ Renal colic	2	05NOV2020	58/C	3	No	O	NA/TC	N	Y/N
		HEPAT	Cholelithiasis/ Gallstones	2	06NOV2020	59/3	1	No	O	NA	R (08NOV2020)	N/N
16-55/ C459100 1 1231 12312577	3^	NEOPL	Metastases to central nervous system/ Brain metastasis	1	28AUG2020	9/C	1	No	O	P/TC	N	Y/N
16-55/ C459100 1 1231 12312593	3^	CARD	Acute coronary syndrome/ Acute coronary syndrome without ST-T segment elevation	2	16SEP2020	6/4	2	No	O	NA/TC	R (19SEP2020)	Y/N
			Bundle branch block right/ right bundle branch block	2	16SEP2020	6/4	1	No	O	NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312611	3^	SKIN	Eczema/ Acute eczema in the cervical region and on the wrists	2	11SEP2020	3/20	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1231 12312617	3^	RESP	Snoring/ primary snoring	2	11SEP2020	2/46	2	No	O	NA/TC/TCN	R (26OCT2020)	N/N
		MUSC	Back pain/ Back pain	2	01OCT2020	22/3	1	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1231 12312639	3^	GENRL	Axillary pain/ right armpit pain	2	29SEP2020	21/2	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1231 12312645	3^	RENAL	Renal colic/ mild renal colic	1	04SEP2020	16/2	1	No	O	NA/TC	R (05SEP2020)	N/N
16-55/ C459100 1 1231 12312647	3^	MUSC	Myalgia/ myalgia in left hemibody predominantly left arm and cervical region	2	10SEP2020	1/23	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1231 12312649	3^	REPRO	Menstruation delayed/ menstrual delay	2	18SEP2020	8/18	1	No	O	NA	R (05OCT2020)	N/N
16-55/ C459100 1 1231 12312666	3^	INJ&P	Procedural dizziness/ post-blood extraction lipothymia (dizziness)	2	07OCT2020	29/1	2	No	O	NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312674	3^	CARD	Sinus tachycardia/ Sinus tachycardia	2	27SEP2020	19/3	2	No	O	NA	R (29SEP2020)	N/N
16-55/ C459100 1 1231 12312683	3^	INFEC	Rhinitis/ RHINITIS	2	13SEP2020	5/8	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C459100 1 1231 12312688	3^	MUSC	Pain in extremity/ Lower limb pain	2	09SEP2020	1/2	1	No	O	NA	R (10SEP2020)	N/N
16-55/ C459100 1 1231 12312712	3^	GASTR	Toothache/ First lower left molar pain	2	20SEP2020	13/6	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1231 12312714	3^	MUSC	Myalgia/ Muscle Pain in left arm	1	20AUG2020	1/6	2	Yes		NA/TC	R (25AUG2020)	N/N
		NERV	Headache/ Headache	1	20AUG2020	1/6	2	Yes		NA/TC	R (25AUG2020)	N/N
		MUSC	Back pain/ LOW BACK PAIN	1	06SEP2020	18/7	2	No	O	NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	06SEP2020	18/7	2	No	O	NA/TC	R (12SEP2020)	N/N
		SKIN	Rash erythematous/ Pruritic erythematous rash of the legs, face, and trunk	2	10SEP2020	2/3	2	No	O	NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312743	3^	GENRL	Chest pain/ precordial pain	2	26SEP2020	18/5	2	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1231 12312747	3^	NERV	Sciatica/ lumbociatalgia	2	12SEP2020	2/2	2	No	O	NA	R (13SEP2020)	N/N
16-55/ C459100 1 1231 12312753	3^	GENRL	Injection site pain/ Injection site pain.	2	16OCT2020	36/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1231 12312759	3^	GENRL	Injection site pain/ Pain at the injection site	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
		GENRL	Fatigue/ fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
			Pyrexia/ Fever	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		MUSC	Arthralgia/ arthralgia	2	12SEP2020	2/C	1	Yes		NA/TC	N	N/N
		NERV	Headache/ headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1231 12312761	3^	NERV	Paraesthesia/ left foot paresthesia	2	31OCT2020	51/2	1	No	O	NA	R (01NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312770	3^	MUSC	Paraesthesia/ right upper limb paresthesia	2	31OCT2020	51/3	1	No	O	NA	R (02NOV2020)	N/N
			Arthralgia/ Left knee pain	2	14SEP2020	4/24	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C459100 1 1231 12312787	3^	GENRL	Pyrexia/ fever	2	12SEP2020	2/1	3	Yes		NA/TC	R (12SEP2020)	N/N
		EAR	Sudden hearing loss/ sudden hearing loss in the right ear	2	02OCT2020	22/15	1	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1231 12312790	3^	NERV	Headache/ headache	1	29AUG2020	9/1	1	No	O	NA	R (29AUG2020)	N/N
16-55/ C459100 1 1231 12312796	3^	RESP	Dysphonia/ Dysphonia	2	28SEP2020	20/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1231 12312826	3^	PSYCH	Anxiety/ exacerbation of anxiety disorder	1	04SEP2020	15/C	1	No	CD	NA/TC/TCN	RG	N/N
16-55/ C459100 1 1231 12312836	3^	MUSC	Arthralgia/ Bilateral hip arthralgia	2	11SEP2020	1/C	1	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312840	3^	NERV	Sciatica/ Lumbociatalgia	2	21SEP2020	11/C	3	No	O	NA/TC/TCN	N	N/N
16-55/ C459100 1 1231 12312850	3^	INJ&P	Animal bite/ Cat bite	2	28SEP2020	18/1	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N
16-55/ C459100 1 1231 12312853	3^	NERV	Headache/ headache	2	16SEP2020	6/38	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C459100 1 1231 12312854	3^	CARD	Arrhythmia supraventricular/ Arrhythmia supraventricular	2	17SEP2020	7/3	4	No	O	NA/TC/TCN	R (19SEP2020)	Y/N
16-55/ C459100 1 1231 12312868	3^	INJ&P	Craniocerebral injury/ minor cranioencephalic trauma	2	08OCT2020	1/1	1	No	O	NA	R (08OCT2020)	N/N
		NERV	Syncope/ syncope	2	08OCT2020	1/1	3	No	O	NA/TCN	R (08OCT2020)	Y/N
16-55/ C459100 1 1231 12312871	3^	INFEC	Skin infection/ Dermal infection	1	27AUG2020	7/9	1	No	O	NA/TC	R (04SEP2020)	N/N
16-55/ C459100 1 1231 12312883	3^	BLOOD	Lymphadenopathy/ Left axillary adenopathy	1	27AUG2020	7/35	1	No	O	NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312892	3^	GENRL	Pyrexia/ Febrile syndrome	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100 1 1231 12312895	3^	PSYCH	Anxiety/ Anxiety crisis	2	29SEP2020	19/1	2	No	O	NA	R (29SEP2020)	N/N
16-55/ C459100 1 1231 12312911	3^	INFEC	Pharyngitis bacterial/ bacterial PHARMINGITIS	2	01OCT2020	23/11	1	No	O	NA	R (11OCT2020)	N/N
16-55/ C459100 1 1231 12312914	3^	CARD	Atrioventricular block second degree/ Second degree AV block (Mobitz II)	2	10NOV2020	58/C	2	No	O	NA	RG	Y/N
16-55/ C459100 1 1231 12312923	3^	NERV	Headache/ Frontal headache with retroorbital pain	1	28AUG2020	8/4	1	No	O	NA	R (31AUG2020)	N/N
		SKIN	Hyperhidrosis/ Sweating	1	28AUG2020	8/4	1	No	O	NA	R (31AUG2020)	N/N
16-55/ C459100 1 1231 12312927	3^	INFEC	Tooth infection/ Tooth infection	2	04OCT2020	24/5	1	No	O	NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1231 12312928	3^	GASTR	Oral mucosa haematoma/ left cheek internal mucosa hematoma	2	14SEP2020	4/2	1	No	O	NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12312930	3^	SKIN	Pruritus/ pruritus in hemiright face, neck, torso, upper back, upper abdomen both arms from shoulder to hand	2	04OCT2020	25/4	1	No	O	NA	R (07OCT2020)	N/N
			Rash/ skin rash in hemiright face, neck, torso, upper back, upper abdomen both arms from shoulder to hand	2	04OCT2020	25/4	1	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1231 12312933	3^	INFECTION	Urinary tract infection/ urinary infection	2	25SEP2020	15/6	1	No	O	NA	R (30SEP2020)	N/N
16-55/ C459100 1 1231 12312941	3^	MUSC	Myalgia/ Generalized Myalgia	1	31AUG2020	11/5	1	No	O	NA	R (04SEP2020)	N/N
16-55/ C459100 1 1231 12312947	3^	METAB	Type 2 diabetes mellitus/ Type 2 diabetes	2	23SEP2020	13/C	1	No	O	NA/TC/TCN	RG	N/N
		VASC	Hypertension/ Hypertension	2	23SEP2020	13/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 1 1231 12312955	3^	RESP	Cough/ cough	2	30SEP2020	22/7	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ mild pain at the injection site	1	23AUG2020	3/3	1	Yes		NA	R (25AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12312982		INFEC	Suspected COVID-19/ Suspected COVID-19 Illness	2	09SEP2020	1/6	3	No	O	NA/TC	R (14SEP2020)	Y/N
		PSYCH	Anxiety/ severe anxiety	2	23SEP2020	15/22	3	No	O	NA/W	R (14OCT2020)	N/N
16-55/ C459100 1 1231 12312984	3^	GENRL	Injection site pain/ Shooting pain at injection site	2	11SEP2020	2/40	1	Yes		NA	R (20OCT2020)	N/N
		GENRL	Injection site pruritus/ itching at the injection site	2	15OCT2020	36/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1231 12312985	3^	MUSC	Back pain/ Low back pain	1	08SEP2020	19/1	3	No	O	NA/TC/TCN	R (08SEP2020)	N/N
16-55/ C459100 1 1231 12312990	3^	GENRL	Pyrexia/ febrile syndrome	1	22AUG2020	2/2	1	Yes		NA/TC	R (23AUG2020)	N/N
16-55/ C459100 1 1231 12312991	3^	MUSC	Muscle contracture/ interscapular muscle contracture in right dorsal region	2	12SEP2020	2/10	2	No	O	NA/TC/TCN	R (21SEP2020)	N/N
		INFEC	Cellulitis/ Cellulitis (left maxillary region)	2	02OCT2020	22/19	1	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C459100	3^	RESP	Asthmatic crisis/ asthmatic crisis	2	15SEP2020	7/23	2	No	O	NA/TC	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12313002	3^	NERV	Paraesthesia/ paresthesias in right upper limb	2	27SEP2020	17/1	1	Yes		NA	R (27SEP2020)	N/N
1 1231 12313014	3^	EAR	Tinnitus/ Bilateral tinnitus	1	24AUG2020	4/5	1	No	O	NA	R (28AUG2020)	N/N
1 1231 12313026	3^	NERV	Migraine/ Migraine	1	22AUG2020	2/1	2	No	O	NA/TC	R (22AUG2020)	N/N
1 1231 12313028		GENRL	Injection site erythema/ Erythema at the injection site	2	12SEP2020	2/4	1	Yes		NA	R (15SEP2020)	N/N
			Injection site lymphadenopathy/ Axillary and cervical lymphadenopathy ipsilateral to the injection site	2	12SEP2020	2/6	1	Yes		NA	R (17SEP2020)	N/N
			Injection site warmth/ slight increase in temperature at injection site	2	12SEP2020	2/4	1	Yes		NA/TC	R (15SEP2020)	N/N
		REPRO	Metrorrhagia/ Metrorrhagia	2	13SEP2020	3/7	1	No	O	NA	R (19SEP2020)	N/N
16-55/ C459100 1 1231 12313034	3^	GENRL	Injection site pain/ Pain at the injection site	1	22AUG2020	1/3	2	Yes		NA/TC	R (24AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Paraesthesia/ paresthesia in left arm	1	22AUG2020	1/3	2	No	O	NA/TC	R (24AUG2020)	N/N
16-55/ C459100 1 1231 12313045	3^	INFEC	Cystitis/ Cystitis	2	20SEP2020	8/5	1	No	O	NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1231 12313061	3^	GENRL	Pyrexia/ fever	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1231 12313065	3^	GASTR	Diarrhoea/ Diarrhea	2	05OCT2020	26/1	1	No	O	NA	R (05OCT2020)	N/N
			Vomiting/ Vomiting	2	05OCT2020	26/1	1	No	O	NA	R (05OCT2020)	N/N
16-55/ C459100 1 1231 12313070	3^	PSYCH	Bruxism/ migraine associated with bruxism	1	22AUG2020	1/32	2	No	O	NA/TC	R (22SEP2020)	N/N
		PSYCH	Bruxism/ migraine associated with bruxism	1	06SEP2020	16/1	2	No	O	NA/TC	R (06SEP2020)	N/N
16-55/ C459100 1 1231 12313087	3^	VASC	Hypotension/ Symptomatic hypotension	1	09SEP2020	19/1	1	No	O	NA	R (09SEP2020)	N/N
16-55/ C459100	3^	GENRL	Pyrexia/ Fever	2	15SEP2020	2/1	3	Yes		NA/TC	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12313088	3^	INFEC	Rhinitis/ Rhinitis	2	05OCT2020	23/6	1	No	O	NA/TC	R (10OCT2020)	N/N
1 1231 12313107	3^	NERV	Headache/ headache	1	06SEP2020	16/11	1	No	O	NA	R (16SEP2020)	N/N
1 1231 12313115	3^	RESP	Rhinitis allergic/ Worsening of Allergic rhinitis	2	01OCT2020	21/2	1	No	O	NA	R (02OCT2020)	N/N
1 1231 12313117	3^	NERV	Headache/ right hemicrania headache	1	30AUG2020	9/2	2	No	O	NA/TC	R (31AUG2020)	N/N
		NERV	Headache/ right hemicrania headache	1	09SEP2020	19/2	2	No	O	NA/TC	R (10SEP2020)	N/N
		NERV	Headache/ Right hemicrania headache	2	20SEP2020	10/1	1	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C459100 1 1231 12313130	3^	MUSC	Bone swelling/ Pain and swelling in the left cheekbone	1	07SEP2020	17/2	1	No	O	NA	R (08SEP2020)	N/N
16-55/ C459100	3^	MUSC	Arthralgia/ Joint pain	1	24AUG2020	3/3	3	No	O	NA/TC	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12313160	3^	NERV	Syncope/ Vasovagal syncope	2	09OCT2020	29/1	1	No	O	NA	R (09OCT2020)	N/N
1 1231 12313163	3^	GASTR	Odynophagia/ Transient discomfort when swallowing	1	02SEP2020	12/1	1	No	O	NA	R (02SEP2020)	N/N
1 1231 12313164	3^	MUSC	Pain in extremity/ Lower right limb pain	2	09OCT2020	27/2	2	No	O	NA/TC	R (10OCT2020)	N/N
1 1231 12313167	3^	SKIN	Erythema nodosum/ erythema nodosum	2	22OCT2020	40/C	1	No	O	NA/TC	N	N/N
1 1231 12313174	3^	GENRL	Chest pain/ nonspecific chest pain	1	29AUG2020	8/3	1	No	O	NA	R (31AUG2020)	N/N
1 1231 12313175		MUSC	Neck pain/ Neck pain	1	18SEP2020	28/44	2	No	O	NA/TC	R (31OCT2020)	N/N
1 1231 12313179	3^	REPRO	Breast pain/ increased pain in the left breast	1	03SEP2020	13/49	1	No	O	NA	R (21OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		BLOOD	Anaemia/ exacerbation of anemia	2	01OCT2020	22/21	1	No	O	NA	R (21OCT2020)	N/N
16-55/ C459100 1 1231 12313180	3^	NERV	Headache/ Headache	2	13NOV2020	64/1	1	No	O	NA	R (13NOV2020)	N/N
16-55/ C459100 1 1231 12313182	3^	CARD	Palpitations/ palpitations	2	24SEP2020	14/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1231 12313191	3^	NERV	Headache/ Headhache	2	14SEP2020	1/13	1	Yes		NA	R (26SEP2020)	N/N
		SKIN	Rash/ skin rash located on the face	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1231 12313193	3^	RENAL	Haematuria/ haematuria	1	25AUG2020	4/29	1	No	O	NA	R (22SEP2020)	N/N
		RENAL	Urinary bladder polyp/ Bladder polyp	2	18SEP2020	9/C	1	No	O	NA/TCN	RG	Y/N
16-55/ C459100 1 1231 12313198	3^	NERV	Migraine/ Exacerbation of migraine	2	20SEP2020	7/6	2	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1231 12313205	3^	NERV	Sciatica/ Worsening of lumboscialgia	2	22SEP2020	13/31	1	No	O	NA/TCN	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12313211	3^	GENRL	Fatigue/ fatigue	1	28AUG2020	7/1	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 1 1231 12313212	3^	GASTR	Diarrhoea/ Diarrhea	2	12SEP2020	3/1	1	Yes		NA	R (12SEP2020)	N/N
			Odynophagia/ Odynophagia	2	12SEP2020	3/3	1	No	O	NA	R (14SEP2020)	N/N
		MUSC	Neck pain/ CERVICAL PAIN	2	14NOV2020	66/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1231 12313216	3^	NERV	Burning sensation/ Burning sensation in left elbow crease	2	18SEP2020	8/9	1	No	O	NA	R (26SEP2020)	N/N
16-55/ C459100 1 1231 12313231	3^	NERV	Headache/ headache	2	09OCT2020	27/2	2	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1231 12313235	3^	GENRL	Injection site pain/ pain in the injection site	2	23SEP2020	11/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1231 12313238	3^	INJ&P	Muscle strain/ righth calf muscle strain	2	07OCT2020	27/6	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C459100	3^	INFEC	Herpes zoster/ Herpes zoster	1	05SEP2020	15/6	1	No	O	NA/TC	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12313249	3^	ENDO	Hypothyroidism/ Exacerbation of hypothyroidism	2	16SEP2020	6/C	2	No	O	NA/TC	RG	N/N
1 1231 12313255	3^	REPRO	Ovarian cyst/ ovarian cyst	2	05OCT2020	26/C	1	No	O	NA	N	N/N
1 1231 12313257	3^	GASTR	Odynophagia/ odynophagia	2	09OCT2020	29/C	1	No	O	NA	N	N/N
1 1231 12313265	3^	INFEC	Papilloma viral infection/ human papillomavirus infection	1	12SEP2020	22/1	1	No	O	NA	R (12SEP2020)	N/N
1 1231 12313284	3^	GENRL	Asthenia/ Asthenia	2	07OCT2020	2/3	1	No	O	NA	R (09OCT2020)	N/N
1 1231 12313289	3^	GASTR	Abdominal pain/ Nonspecific abdominal pain	2	09OCT2020	27/12	1	No	O	NA	R (20OCT2020)	N/N
1 1231 12313290	3^	GENRL	Pyrexia/ FEVER (39 Degrees C)	2	11SEP2020	1/4	3	Yes		NA/TC	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GASTR	Diarrhoea/ DIARRHEA	2	15SEP2020	5/3	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1231 12313314	3^	NERV	Presyncope/ Vasovagal episode	2	09OCT2020	30/1	2	No	O	NA	R (09OCT2020)	N/N
16-55/ C459100 1 1231 12313316	3^	SURG	Cataract operation/ left eye cataract surgery	2	25SEP2020	15/1	2	No	O	NA	R (25SEP2020)	N/N
16-55/ C459100 1 1231 12313326	3^	PSYCH	Insomnia/ insomnia	2	29SEP2020	17/18	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1231 12313327	3^	GENRL	Injection site pruritus/ itching at the injection site	1	24AUG2020	2/15	1	Yes		NA/TC	R (07SEP2020)	N/N
16-55/ C459100 1 1231 12313329	3^	IMMUN	Seasonal allergy/ seasonal allergy	1	06SEP2020	15/48	1	No	O	NA/TC	R (23OCT2020)	N/N
		EAR	Allergic otitis media/ allergic otitis media	2	06OCT2020	24/33	1	No	O	NA	R (07NOV2020)	N/N
		GASTR	Nausea/ nausea	2	08OCT2020	26/2	1	No	CD	NA	R (09OCT2020)	N/N
16-55/ C459100 1 1231 12313335	3^	NERV	Dizziness/ DIZZINESS	2	12OCT2020	30/1	1	No	O	NA	R (12OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12313340	3^	VASC	Haematoma/ Hematoma in left deltoid.	1	23AUG2020	1/8	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 1 1231 12313345	3^	MUSC	Back pain/ low back pain	2	25SEP2020	15/8	1	No	O	NA	R (02OCT2020)	N/N
		MUSC	Neck pain/ cervicalgia	2	12OCT2020	32/31	2	No	O	NA/TC/TCN	R (11NOV2020)	N/N
		UNC	ANEMIC SYNDROME@@/ Anemic syndrome	2	12OCT2020	32/C	1	No	O	NA/TC	N	N/N
		EAR	Tinnitus/ bilateral tinnitus	2	13OCT2020	33/C	2	No	O	NA	N	N/N
16-55/ C459100 1 1231 12313353	3^	MUSC	Back pain/ Right back pain	1	27AUG2020	5/4	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C459100 1 1231 12313356	3^	INFEC	Rhinitis/ Rhinitis	2	14SEP2020	2/34	1	No	O	NA	R (17OCT2020)	N/N
16-55/ C459100 1 1231 12313357	3^	GENRL	Pyrexia/ Febrile Syndrome	1	25AUG2020	3/1	3	Yes		NA/TC	R (25AUG2020)	N/N
16-55/ C459100 1 1231 12313370	3^	NERV	Headache/ Headache	2	20SEP2020	8/2	2	No	O	NA/TC	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12313386	3^	MUSC	Muscle contracture/ Cervical contracture	2	02OCT2020	22/3	2	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 1231 12313395	3^	RESP	Rhinitis allergic/ allergic rhinitis	1	04OCT2020	43/2	1	No	O	NA	R (05OCT2020)	N/N
16-55/ C459100 1 1231 12313400	3^	CARD	Palpitations/ Palpitations	2	10OCT2020	28/1	1	No	O	NA	R (10OCT2020)	N/N
		VASC	Hypertension/ Hypertension	2	10OCT2020	28/1	1	No	O	NA	R (10OCT2020)	N/N
16-55/ C459100 1 1231 12313404	3^	NERV	Headache/ Headache	2	13SEP2020	1/8	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100 1 1231 12313406	3^	GENRL	Fatigue/ Fatigue	1	24AUG2020	2/2	1	Yes		NA	R (25AUG2020)	N/N
16-55/ C459100 1 1231 12313419	3^	SKIN	Acne/ Acne	1	05SEP2020	14/3	1	No	O	NA/TC	R (07SEP2020)	N/N
16-55/ C459100 1 1231 12313429	3^	GENRL	Injection site pain/ Injection Site Pain	1	23AUG2020	1/7	2	Yes		NA/TC	R (29AUG2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12313430	3^	INFEC	Vulvovaginal candidiasis/ vulvovaginal candidiasis	2	12OCT2020	29/4	1	No	O	NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1231 12313432	3^	SKIN	Acne/ acne exacerbation	2	02NOV2020	53/C	1	Yes		NA/TC	N	N/N
16-55/ C459100 1 1231 12313437	3^	SKIN	Pityriasis rosea/ Pityriasis rosea	2	29SEP2020	17/30	2	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C459100 1 1231 12313454	3^	GENRL	Pyrexia/ Fever	1	23AUG2020	1/2	1	Yes		NA/TC	R (24AUG2020)	N/N
		INJ&P	Ligament sprain/ right ankle sprain	1	12SEP2020	21/26	3	No	O	NA/TC	R (07OCT2020)	N/N
		INFEC	Furuncle/ boils	1	02NOV2020	72/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1231 12313465	3^	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	08OCT2020	25/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1231 12313467	3^	SURG	Tooth extraction/ extraction of 2 teeth	1	22SEP2020	31/1	1	No	O	NA/TC/TCN	R (22SEP2020)	N/N
16-55/ C459100	3^	MUSC	Plantar fasciitis/ left plantar fasciitis	1	21SEP2020	30/8	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12313470	3^	MUSC	Myalgia/ Deltoid pain	1	06SEP2020	15/1	1	No	O	NA/TCN	R (06SEP2020)	N/N
1 1231 12313471		VASC	Haematoma/ hematoma in left deltoid region	2	18SEP2020	6/3	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C459100		MUSC	Muscle contracture/ cervical contracture	2	07NOV2020	56/7	2	No	O	NA/TC/TCN	R (13NOV2020)	N/N
16-55/ C459100	3^	SKIN	Rash/ GENERALIZED RASH	1	12SEP2020	21/7	1	No	O	NA	R (18SEP2020)	N/N
1 1231 12313489												
16-55/ C459100	3^	SOCCI	Stress at work/ Work Stress	1	05OCT2020	44/32	1	No	O	NA/TC	R (05NOV2020)	N/N
1 1231 12313492												
16-55/ C459100	3^	INFEC	Furuncle/ Furunculosis in axillary and left inginal region	1	14OCT2020	53/11	1	No	O	NA/TC	R (24OCT2020)	N/N
1 1231 12313497												
16-55/ C459100	3^	INFEC	Tooth infection/ upper left second molar infection	2	01OCT2020	17/4	1	No	O	NA/TC	R (04OCT2020)	N/N
1 1231 12313501												
16-55/ C459100	3^	NERV	Headache/ Headache	1	04SEP2020	13/2	2	No	O	NA/TC	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12313507		GENRL	Injection site pain/ injection site pain in left arm	2	13SEP2020	1/26	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1231 12313508	3^	MUSC	Arthralgia/ arthralgias	2	01OCT2020	15/37	1	No	O	NA	R (06NOV2020)	N/N
16-55/ C459100 1 1231 12313512	3^	EAR	Vertigo/ Vertiginous syndrome	1	05SEP2020	14/1	3	No	O	NA/TCN	R (05SEP2020)	N/N
16-55/ C459100 1 1231 12313513	3^	GENRL	Asthenia/ asthenia	2	22SEP2020	10/6	2	No	O	NA	R (27SEP2020)	N/N
			Pyrexia/ fever	2	22SEP2020	10/2	1	No	O	NA/TC/TCN	R (23SEP2020)	N/N
		NERV	Headache/ headache	2	22SEP2020	10/3	1	No	O	NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1231 12313516	3^	INFEC	Cellulitis/ facial cellulitis	1	23AUG2020	1/6	1	No	O	NA/TC	R (28AUG2020)	N/N
16-55/ C459100 1 1231 12313551	3^	MUSC	Muscle contracture/ Cervical contracture	1	21OCT2020	60/1	2	No	O	NA	R (21OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	1	21OCT2020	60/1	2	No	O	NA/TC	R (21OCT2020)	N/N
16-55/ C459100 1 1231 12313575	3^	MUSC	Tendonitis/ Tendonitis	1	24AUG2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1231 12313576	3^	NERV	Sciatica/ Lumbociatalgia	2	03OCT2020	23/1	2	No	O	NA	R (03OCT2020)	N/N
16-55/ C459100 1 1231 12313605	3^	GENRL	Fatigue/ Fatigue	1	23AUG2020	1/3	1	Yes		NA	R (25AUG2020)	N/N
16-55/ C459100 1 1231 12313631	3^	REPRO	Pruritus genital/ genital itching	2	15SEP2020	3/46	1	No	O	NA/TC	R (30OCT2020)	N/N
16-55/ C459100 1 1231 12313636	3^	INV	Body temperature increased/ Body temperature increased	2	01OCT2020	18/2	1	No	O	NA	R (02OCT2020)	N/N
16-55/ C459100 1 1231 12313637	3^	NERV	Paraesthesia/ Paresthesia in the scapular and lumbar region	2	13SEP2020	1/30	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C459100 1 1231 12313644	3^	SKIN	Rash/ Rash in the upper dorsal region	2	06OCT2020	24/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12313646	3^	MUSC	Myalgia/ Muscle pain	2	17SEP2020	2/2	3	No	O	NA/TC	R (18SEP2020)	N/N
		MUSC	Trigger finger/ TRigger Finger	2	24SEP2020	9/16	2	No	O	NA/TC	R (09OCT2020)	N/N
		EYE	Conjunctival haemorrhage/ subconjunctival hemorrhage	2	02OCT2020	17/3	1	No	O	NA/TC	R (04OCT2020)	N/N
		INJ&P	Skin laceration/ Cutting wound second phalanx of left hand	2	11OCT2020	26/4	2	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1231 12313653	3^	NERV	Ischaemic stroke/ Ischemic Stroke	2	06NOV2020	55/C	3	No	O	NA	RG	Y/N
16-55/ C459100 1 1231 12313684	3^	MUSC	Arthralgia/ left shoulder arthralgia	1	27AUG2020	4/8	1	No	O	NA	R (03SEP2020)	N/N
16-55/ C459100 1 1231 12313685	3^	SKIN	Rash/ RASH ON LEFT ARM AND HEMITHORAX	2	18SEP2020	6/7	1	No	O	NA	R (24SEP2020)	N/N
16-55/ C459100 1 1231 12313693	3^	GASTR	Toothache/ Left hemiarcaled upper premolar tooth pain	2	07OCT2020	25/15	1	No	O	NA/TC/TCN	R (21OCT2020)	N/N
16-55/ C459100	3^	NERV	Dysgeusia/ Dysgeusia	2	19SEP2020	7/17	1	No	O	NA	R (05OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12313695	3^	GASTR	Toothache/ Left lower third molar tooth pain	2	03OCT2020	19/2	1	No	O	NA	R (04OCT2020)	N/N
1 1231 12313702	3^	NERV	Migraine/ Migraine exacerbation	2	03OCT2020	21/4	2	No	O	NA	R (06OCT2020)	N/N
1 1231 12313718	3^	MUSC	Arthralgia/ Stabbing pain in scapular region bilateral intermittent	2	05OCT2020	23/15	2	No	O	NA/TC	R (19OCT2020)	N/N
1 1231 12313756		GENRL	Pain/ stabbing nonspecific trunk pain	2	10OCT2020	28/10	1	No	O	NA/TC	R (19OCT2020)	N/N
16-55/ C459100 1 1231 12313758	3^	MUSC	Back pain/ muscle pain in the back	1	22OCT2020	60/4	1	No	O	NA/TC	R (25OCT2020)	N/N
16-55/ C459100 1 1231 12313759	3^	GASTR	Diarrhoea/ Diarrhea	2	16OCT2020	33/2	2	No	O	NA/TC/TCN	R (17OCT2020)	N/N
16-55/ C459100 1 1231 12313773	3^	GENRL	Asthenia/ Asthenia	1	24AUG2020	1/3	1	Yes		NA	RS (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Vaccination site pain/ Vaccine injection site pain	1	24AUG2020	1/63	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 1 1231 12313777	3^	BLOOD	Lymphadenopathy/ left supraclavicular and axillary adenomegaly	2	16SEP2020	2/8	2	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1231 12313778	3^	RESP	Allergic sinusitis/ Seasonal sinusitis	2	22SEP2020	10/6	1	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C459100 1 1231 12313780	3^	GASTR	Aphthous ulcer/ oral aphthae	2	15SEP2020	3/8	2	No	O	NA/TC	R (22SEP2020)	N/N
16-55/ C459100 1 1231 12313818	3^	GASTR	Toothache/ Toothache	2	06OCT2020	24/11	1	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1231 12313825	3^	VASC	Intermittent claudication/ intermittent claudication	1	27AUG2020	3/21	2	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1231 12313831	3^	VASC	Varicose vein/ Worsening pain from varicose veins	2	07OCT2020	23/4	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1231 12313832	3^	GENRL	Asthenia/ asthenia	1	26AUG2020	2/2	1	No	O	NA	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12313836	3^	MUSC	Back pain/ low back pain	2	07OCT2020	22/35	1	No	O	NA/TC/TCN	R (10NOV2020)	N/N
16-55/ C459100 1 1231 12313854	3^	GENRL	Injection site pain/ Pain at the injection site	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/Y
16-55/ C459100 1 1231 12313862	3^	MUSC	Myalgia/ myalgia	2	20SEP2020	7/23	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C459100 1 1231 12313877	3^	CARD	Angina pectoris/ angina	2	09OCT2020	24/8	1	No	CD	NA/TC	RS (16OCT2020)	N/N
		INFEC	Otitis media acute/ Left acute otitis media	2	09OCT2020	24/8	1	No	O	NA/TC	RS (16OCT2020)	N/N
16-55/ C459100 1 1231 12313879	3^	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/Y
		INJ&P	Exposure during pregnancy/ Exposure to Investigation product during pregnancy	1	10SEP2020	17/C		No	O	NA	UNK	N/N
		NERV	Headache/ headache	2	14SEP2020	2/9	3	No	O	NA/TC	R (22SEP2020)	N/N
16-55/ C459100	3^	BLOOD	Lymphadenopathy/ right axillary adenopathy	2	18SEP2020	3/5	1	No	O	NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12313884												
16-55/ C459100 1 1231 12313893	3^	GENRL	Vessel puncture site haematoma/ Blood draw site hematoma on left arm	2	14OCT2020	32/8	1	No	O	NA	R (21OCT2020)	N/N
16-55/ C459100 1 1231 12313896	3^	GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/Y
		GASTR	Dental caries/ Caries in premolar and molar	1	01SEP2020	8/53	2	No	O	NA/TC/TCN	R (23OCT2020)	N/N
16-55/ C459100 1 1231 12313902	3^	INJ&P	Contusion/ Traumatic contusion in the arms	1	04SEP2020	11/9	2	No	O	NA/TCN	R (12SEP2020)	N/N
			Contusion/ Traumatic contusion in the trunk	1	04SEP2020	11/9	2	No	O	NA/TC/TCN	R (12SEP2020)	N/N
			Contusion/ Traumatic contusion on the face	1	04SEP2020	11/9	2	No	O	NA/TC/TCN	R (12SEP2020)	N/N
		PSYCH	Panic attack/ Panic attack	1	04SEP2020	11/42	2	No	O	NA/TC/TCN	R (15OCT2020)	N/N
16-55/ C459100 1 1231 12313904	3^	CARD	Palpitations/ Intermittent Palpitations.	2	15SEP2020	3/6	1	No	O	NA	R (20SEP2020)	N/N
		INV	Body temperature increased/ Body temperature increased	2	15SEP2020	3/6	1	No	O	NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12313916	3^	MUSC	Back pain/ Low back pain	2	30SEP2020	18/26	1	No	O	NA/TC	R (25OCT2020)	N/N
16-55/ C459100 1 1231 12313921	3^	MUSC	Muscle contracture/ Cervical muscular contracture	1	07SEP2020	14/6	1	No	O	NA/TC/TCN	R (12SEP2020)	N/N
16-55/ C459100 1 1231 12313925	3^	RESP	Interstitial lung disease/ Right lung interstitial pneumonia	1	02SEP2020	9/8	2	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C459100 1 1231 12313927	3^	MUSC	Arthralgia/ left shoulder pain	2	18SEP2020	6/C	2	No	O	NA/TC	N	N/N
			Rotator cuff syndrome/ left rotator cuff tendonitis	2	18SEP2020	6/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C459100 1 1231 12313931	3^	GASTR	Diarrhoea/ diarrhea	1	28AUG2020	4/3	1	No	O	NA	R (30AUG2020)	N/N
		MUSC	Synovial cyst/ ganglion in right wrist joint	2	22SEP2020	10/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1231 12313935	3^	GENRL	Injection site pain/ mild pain at the injection site	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
16-55/ C459100	3^	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	23/2	1	No	O	NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12313939												
16-55/ C459100	3^	NERV	Headache/ Headache	1	30AUG2020	6/50	1	No	O	NA/TC	R (18OCT2020)	N/N
1 1231 12313941												
16-55/ C459100	3^	GENRL	Swelling face/ Swelling in cheeks	2	16OCT2020	32/1	1	No	O	NA/TC	R (16OCT2020)	N/N
1 1231 12313960												
16-55/ C459100	3^	MUSC	Tendon disorder/ right shoulder tendinosis	1	07SEP2020	14/3	1	No	O	NA/TC	R (09SEP2020)	N/N
1 1231 12313967												
16-55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	2/3	2	Yes		NA/TC	R (28AUG2020)	N/N
1 1231 12313968												
16-55/ C459100	3^	INJ&P	Ligament sprain/ right ankle sprain	2	30SEP2020	16/28	2	No	O	NA/TCN	R (27OCT2020)	N/N
1 1231 12313984												
16-55/ C459100	3^	INFEC	Rhinitis/ rhinitis	2	24SEP2020	9/19	1	No	O	NA/TC	R (12OCT2020)	N/N
1 1231 12313989												
16-55/ C459100	3^	PSYCH	Depression/ Worsening Depression	2	14OCT2020	30/21	2	No	O	NA/TC/TCN	R (03NOV2020)	N/N
1 1231 12313993												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12314010	3^	INJ&P	Skin injury/ ERYTHEMATOUS AND FLAKY SKIN INJURIES IN TRUNK AND THIGHS	2	02OCT2020	18/25	1	No	O	NA	R (26OCT2020)	N/N
16-55/ C459100 1 1231 12314022	3^	GASTR	Dry mouth/ xerostomia	2	12OCT2020	28/C	1	No	O	NA/TCN	N	N/N
16-55/ C459100 1 1231 12314032	3^	MUSC	Musculoskeletal chest pain/ muscle-type chest pain	2	22SEP2020	9/3	1	No	O	NA	R (24SEP2020)	N/N
		GENRL	Chest pain/ Intermittent chest pain in the right pectoral	2	06OCT2020	23/2	1	No	O	NA	R (07OCT2020)	N/N
		MUSC	Myalgia/ muscle pain in the upper inner third of the righth arm	2	06OCT2020	23/2	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C459100 1 1231 12314033	3^	BLOOD	Lymphadenopathy/ Left axillary adenopathy	1	01SEP2020	8/17	2	No	O	NA	R (17SEP2020)	N/N
16-55/ C459100 1 1231 12314059	3^	INJ&P	Exposure during pregnancy/ exposure during pregnancy	1	31AUG2020	7/C		No	O	NA	UNK	N/N
16-55/ C459100 1 1231 12314073	3^	SKIN	Rash papular/ Papular rash in deltoid region of the right arm.	2	17OCT2020	33/4	1	No	O	NA/TC/TCN	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12314075	3^	RENAL	Pollakiuria/ NOCTURNE POLLAKIURIA	1	28AUG2020	3/62	2	No	O	NA	R (28OCT2020)	N/N
		MUSC	Back pain/ LOW BACK PAIN WORSENING	1	30AUG2020	5/24	2	No	O	NA/TC	R (22SEP2020)	N/N
16-55/ C459100 1 1231 12314084	3^	INFEC	Tooth infection/ Left wisdom tooth infection	1	28AUG2020	3/27	2	No	O	NA/TC/TCN	R (23SEP2020)	N/N
16-55/ C459100 1 1231 12314104	3^	INJ&P	Chest injury/ Trauma to the posterior region of the right rib cage	2	05NOV2020	52/1	1	No	O	NA/TC	R (05NOV2020)	N/N
		MUSC	Musculoskeletal chest pain/ pain in right posterior rib	2	05NOV2020	52/C	2	No	O	NA/TC	RG	N/N
		NEOPL	Lipoma/ Lipoma in the right mid-axillary line	2	06NOV2020	53/1	1	No	O	NA	R (06NOV2020)	N/N
16-55/ C459100 1 1231 12314111	3^	EAR	Vertigo/ Vertigo	1	26AUG2020	1/13	1	No	O	NA/TC/TCN	R (07SEP2020)	N/N
		MUSC	Myalgia/ myalgia	1	26AUG2020	1/6	2	Yes		NA/TC/TCN	R (31AUG2020)	N/N
16-55/ C459100 1 1231 12314128	3^	BLOOD	Lymphadenopathy/ Left cervical adenopathy	1	27AUG2020	2/37	1	No	O	NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12314132	3^	EAR	Ear pain/ left otalgia	1	27AUG2020	2/3	1	No	O	NA	R (29AUG2020)	N/N
		GENRL	Injection site pain/ pain at the injection site.	1	11SEP2020	17/53	1	Yes		NA/TC	R (02NOV2020)	N/N
16-55/ C459100 1 1231 12314135	3^	NERV	Paraesthesia/ tingling in left arm	1	11SEP2020	17/C	1	Yes		NA/TC	N	N/N
		NERV	Headache/ Headache	2	12OCT2020	29/2	2	No	O	NA/TC	RS (13OCT2020)	N/N
16-55/ C459100 1 1231 12314137	3^	GENRL	Asthenia/ asthenia	2	19SEP2020	6/3	3	No	O	NA	R (21SEP2020)	N/N
16-55/ C459100 1 1231 12314143	3^	EYE	Blepharospasm/ blepharospasm	2	30SEP2020	17/3	1	No	O	NA	R (02OCT2020)	N/N
		SURG	Dental care/ dental treatment	2	13OCT2020	30/1	1	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C459100 1 1231 12314152	3^	ENDO	Hypothyroidism/ Hypothyroidism	1	01SEP2020	7/46	1	No	O	NA/TC	R (16OCT2020)	N/N
		GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux	1	01SEP2020	7/46	1	No	O	NA/TC	R (16OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12314155	3^	INJ&P	Ligament sprain/ Right ankle sprain	2	19SEP2020	6/6	2	No	O	NA/TC/TCN	R (24SEP2020)	N/N
16-55/ C459100 1 1231 12314188	3^	REPRO	Menstruation delayed/ Menstrual delay	2	15SEP2020	2/58	1	No	O	NA/TC	R (11NOV2020)	N/N
16-55/ C459100 1 1231 12314198	3^	GENRL	Injection site pain/ Local pain at injection site	1	27AUG2020	2/2	2	Yes		NA/TC	R (28AUG2020)	N/N
16-55/ C459100 1 1231 12314202	3^	EYE	Conjunctival haemorrhage/ Subconjunctival hemorrhage left eye	2	12OCT2020	29/14	1	No	O	NA	R (25OCT2020)	N/N
16-55/ C459100 1 1231 12314203	3^	INFEC	Pustule/ Pustulosis in upper limbs and lumbar area.	2	17SEP2020	3/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1231 12314212	3^	INJ&P	Joint injury/ Right knee trauma	2	29SEP2020	14/42	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N
16-55/ C459100 1 1231 12314223	3^	GASTR	Odynophagia/ odynophagia	2	29SEP2020	16/3	1	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C459100	3^	NERV	Sciatica/ Flare-up of sciatica	2	19SEP2020	5/52	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12314224		MUSC	Arthralgia/ Migratory arthralgias in upper limbs	2	10OCT2020	26/4	2	No	O	NA	R (13OCT2020)	N/N
16-55/ C459100 1 1231 12314229	3^	GASTR	Irritable bowel syndrome/ irritable bowel	1	01SEP2020	7/45	1	No	O	NA/TC/TCN	R (15OCT2020)	N/N
16-55/ C459100 1 1231 12314251	3^	NERV	Headache/ headache	2	23SEP2020	8/4	1	No	O	NA	R (26SEP2020)	N/N
16-55/ C459100 1 1231 12314256	3^	INJ&P	Radius fracture/ Intra-articular Left Radius Fracture	2	09OCT2020	3/5	2	No	O	NA/TC/TCN	R (13OCT2020)	N/N
		SOCCI	High risk sexual behaviour/ Risky sexual behavior	2	24OCT2020	18/1	1	No	O	NA/TC	R (24OCT2020)	N/N
16-55/ C459100 1 1231 12314263	3^	GENRL	Injection site papule/ multiple small itchy papule located on the left arm, extending from the injection site to the elbow	1	31AUG2020	6/3	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Injection site papule/ multiple small itchy papules located on the left arm, extending from the injection site to the elbow	2	18SEP2020	5/3	1	Yes		NA/TC	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11231 12314265	3^	MUSC	Arthralgia/ Arthralgies	1	31AUG2020	6/C	2	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 11231 12314267	3^	INFEC	Tonsillitis/ tonsillitis	2	08OCT2020	25/6	2	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C459100 11231 12314269	3^	GASTR	Stomatitis/ stomatitis	2	19SEP2020	2/19	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C459100 11231 12314270	3^	RENAL	Dysuria/ Dysuria	2	01OCT2020	18/39	1	No	O	NA	R (08NOV2020)	N/N
16-55/ C459100 11231 12314277	3^	MUSC	Temporomandibular joint syndrome/ Temporomandibular dysfunction	2	23SEP2020	8/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C459100 11231 12314278	3^	GENRL	Pyrexia/ fever	2	15SEP2020	2/2	3	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 11231 12314290	3^	GASTR	Abdominal pain upper/ Epigastralgia	1	28AUG2020	3/15	2	No	O	NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12314297	3^	METAB	Diabetes mellitus inadequate control/ Uncompensated diabetes	2	17SEP2020	4/14	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1231 12314298	3^	GASTR	Gastritis/ Worsening gastritis	1	27AUG2020	2/3	1	No	O	NA/TC	R (29AUG2020)	N/N
16-55/ C459100 1 1231 12314329	3^	INFEC	Pharyngitis/ Pharyngitis	1	27AUG2020	2/5	2	No	O	NA/TC	R (31AUG2020)	N/N
16-55/ C459100 1 1231 12314343	3^	INFEC	Pharyngotonsillitis/ Putaceous pharyngotonsillitis	1	29AUG2020	4/4	2	No	O	NA/TC	R (01SEP2020)	N/N
16-55/ C459100 1 1231 12314358	3^	MUSC	Musculoskeletal chest pain/ Chest muscle pain	2	24SEP2020	11/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1231 12314360	3^	GENRL	Chills/ Chills	2	09OCT2020	24/1	1	No	O	NA	R (09OCT2020)	N/N
			Fatigue/ Fatigue	2	09OCT2020	24/1	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C459100 1 1231 12314368	3^	BLOOD	Lymphadenopathy/ Supraclavicular adenopathy (left)	1	29AUG2020	4/56	1	No	O	NA/TC	R (23OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12314395	3^	RESP	Tonsillar hypertrophy/ swollen tonsils	2	18SEP2020	3/21	1	No	O	NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1231 12314395	3^	REPRO	Haemospermia/ Hemospermia	2	26SEP2020	12/1	1	No	O	NA	R (26SEP2020)	N/N
16-55/ C459100 1 1231 12314400	3^	RESP	Asthma/ asthma exacerbation	2	26SEP2020	11/5	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C459100 1 1231 12314405	3^	EAR	Vertigo/ two second-long episodes of vertigo	1	27AUG2020	1/1	1	No	O	NA	R (27AUG2020)	N/N
16-55/ C459100 1 1231 12314407	3^	GENRL INJ&P	Injection site pain/ local pain at the injection site Multiple injuries/ Polytrauma	1 2	27AUG2020 20SEP2020	1/3 5/C	1 3	Yes No	 O	NA NA/TC/TCN	R RG	N/N Y/N
16-55/ C459100 1 1231 12314416	3^	RESP	Epistaxis/ Epistaxis	2	20SEP2020	5/30	2	No	O	NA/TCN	R (19OCT2020)	N/N
16-55/ C459100 1 1231 12314416	3^	VASC	Subgaleal haematoma/ subgaleal hematoma	2	20SEP2020	5/C	2	No	O	NA/TCN	RG	N/N
16-55/ C459100 1 1231 12314416	3^	NERV	Sciatica/ lumbosciatica	1	11SEP2020	16/54	1	No	O	NA/TC	R (03NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12314421	3^	INFEC	Urinary tract infection/ urinary infection	2	20OCT2020	36/6	1	No	O	NA	R (25OCT2020)	N/N
16-55/ C459100 1 1231 12314434	3^	VASC	Hypertension/ arterial hypertension	1	01SEP2020	6/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1231 12314435	3^	GENRL	Asthenia/ asthenia	1	27AUG2020	1/1	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 1 1231 12314436	3^	GENRL	Pyrexia/ fever	2	15SEP2020	1/2	3	No	O	NA	R (16SEP2020)	N/N
16-55/ C459100 1 1231 12314450	3^	INFEC	Anal fistula infection/ anal fistula acute infection	1	15SEP2020	20/5	2	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1231 12314464	3^	EAR	Tinnitus/ tinnitus bilateral, intermittent	1	10SEP2020	15/38	1	No	O	NA	R (17OCT2020)	N/N
		CARD	Palpitations/ PALPITATIONS	2	16SEP2020	1/13	1	No	O	NA	R (28SEP2020)	N/N
		GASTR	Dental caries/ Dental Cavities	2	10OCT2020	25/8	1	No	O	NA/TC/TCN	R (17OCT2020)	N/N
16-55/ C459100	3^	INFEC	Periodontitis/ Right lower molar periodontitis	1	28AUG2020	2/7	2	No	O	NA/TC	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12314474	3^	GENRL	Fatigue/ fatigue	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
1 1231 12314477			Injection site pain/ Injection site pain	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
		MUSC	Myalgia/ Generalized muscle pain	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
		RESP	Rhinorrhoea/ rhinorrhea	2	23SEP2020	6/11	1	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C459100	3^	INJ&P	Penis injury/ PENIS INJURY	2	15SEP2020	1/8	1	No	O	NA/TCN	R (22SEP2020)	N/N
1 1231 12314482	3^	RESP	Rhinitis allergic/ Allergic rhinitis	2	07OCT2020	23/3	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C459100	3^	INFEC	Rhinitis/ Rhinitis	2	28SEP2020	13/3	1	No	O	NA/TC	R (30SEP2020)	N/N
1 1231 12314499		MUSC	Back pain/ low back pain	2	30SEP2020	15/6	1	No	O	NA	R (05OCT2020)	N/N
		MUSC	Pain in extremity/ Nonspecific upper limb pain.	2	18OCT2020	33/2	2	No	O	NA/TC	R (19OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12314511	3^	GENRL	Pyrexia/ Fever	1	28AUG2020	2/3	2	Yes		NA/TC	R (30AUG2020)	N/N
		GASTR	Stomatitis/ Stomatitis	1	07SEP2020	12/6	1	No	O	NA	R (12SEP2020)	N/N
16-55/ C459100 1 1231 12314513	3^	NERV	Headache/ Headache	2	15SEP2020	1/15	1	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C459100 1 1231 12314515	3^	GENRL	Axillary pain/ Regional pain (left axillary hollow)	2	29OCT2020	45/3	1	No	O	NA	R (31OCT2020)	N/N
16-55/ C459100 1 1231 12314526	3^	NERV	Dizziness/ Dizziness	2	06OCT2020	20/1	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C459100 1 1231 12314528	3^	INFEC	Herpes zoster/ HERPES ZOSTER RIGHT THORACIC of one dermatome	2	01NOV2020	48/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1231 12314529	3^	MUSC	Myalgia/ Generalized muscle pain	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1231 12314531	3^	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	01OCT2020	4/C		No	O	NA	UNK	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12314542	3^	MUSC	Arthralgia/ Arthralgia	1	01SEP2020	6/50	1	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C459100 1 1231 12314550	3^	MUSC	Pain in extremity/ Pain in right upper limb	2	16OCT2020	31/C	2	No	O	NA/TC/TCN	RG	N/N
		NERV	Neuropathy peripheral/ Right upper limb neuropathy	2	16OCT2020	31/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1231 12314553	3^	INFEC	Furuncle/ furunculosis	1	29AUG2020	3/16	2	No	O	NA/TC	R (13SEP2020)	N/N
16-55/ C459100 1 1231 12314554	3^	MUSC	Neck pain/ right cervicalgia	1	07SEP2020	12/2	1	No	O	NA	R (08SEP2020)	N/N
16-55/ C459100 1 1231 12314562	3^	BLOOD	Lymphadenopathy/ left submandibular adenopathy.	2	03OCT2020	18/11	1	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C459100 1 1231 12314573	3^	VASC	Haematoma/ hematoma 8 cm in diameter, external face of right leg	2	17OCT2020	33/6	1	No	O	NA/TC	R (22OCT2020)	N/N
16-55/ C459100 1 1231 12314575	3^	RESP	Asthma/ asthma attack	1	05SEP2020	10/2	2	No	O	NA/TC	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12314582		GENRL	Injection site pain/ Burning at injection site	1	08OCT2020	43/1	1	Yes		NA	R (08OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		NERV	Trigeminal neuralgia/ Trigeminal neuralgia	2	17OCT2020	31/10	2	No	O	NA/TC	R (26OCT2020)	N/N
		GASTR	Abdominal pain upper/ Epigastralgia	2	15OCT2020	31/5	1	No	O	NA	R (19OCT2020)	N/N
		SKIN	Rash/ Rash in torso and arms.	1	01SEP2020	6/10	1	No	O	NA	R (10SEP2020)	N/N
		INFEC	Orchitis/ Epididymitis orchitis	2	21OCT2020	37/C	2	No	O	NA/TC	N	N/N
		CARD	Tachycardia/ resting tachycardia	1	29AUG2020	3/1	1	No	O	NA	R (29AUG2020)	N/N
		GENRL	Injection site pain/ Local pain at injection site	1	29AUG2020	2/2	1	Yes		NA/TC	R (30AUG2020)	N/N
		MUSC	Back pain/ Low back pain	2	05OCT2020	20/4	1	No	O	NA/TC	RS (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12314678	3^	CARD	Tachycardia/ tachycardia	1	29AUG2020	2/3	1	No	O	NA	R (31AUG2020)	N/N
1 1231 12314679		MUSC	Neck pain/ Neck pain	1	01SEP2020	5/3	1	No	O	NA/TC/TCN	R (03SEP2020)	N/N
16-55/ C459100	3^	GENRL	Asthenia/ asthenia	1	05SEP2020	9/3	2	No	O	NA/TC	R (07SEP2020)	N/N
1 1231 12314699		NERV	Headache/ headache	2	16SEP2020	1/24	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100	3^	GENRL	Pyrexia/ fever	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N
1 1231 12314712												
16-55/ C459100	3^	GASTR	Diarrhoea/ loose stools	2	30SEP2020	15/3	1	No	O	NA	R (02OCT2020)	N/N
1 1231 12314719												
16-55/ C459100	3^	INFEC	Folliculitis/ Left Groin Folliculitis	2	04OCT2020	19/8	1	No	O	NA/TC	R (11OCT2020)	N/N
1 1231 12314730												
16-55/ C459100	3^	INJ&P	Meniscus injury/ Right knee meniscus tear	2	22SEP2020	7/46	2	No	O	NA/TC/TCN	R (06NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12314731	3^	EAR	Ear pain/ Right otalgia	2	14OCT2020	29/14	1	No	O	NA/TC	R (27OCT2020)	N/N
1 1231 12314756	3^	NERV	Headache/ headache	2	15OCT2020	30/1	1	No	O	NA/TC	R (15OCT2020)	N/N
1 1231 12314764	3^	GENRL	Pyrexia/ fever	2	18SEP2020	2/1	3	Yes		NA/TC/TCN	R (18SEP2020)	N/N
1 1231 12314768	3^	GASTR	Gastritis/ Gastritis	2	08OCT2020	23/11	1	No	O	NA/TC	R (18OCT2020)	N/N
1 1231 12314771	3^	EYE	Chalazion/ chalazion	2	24SEP2020	9/3	1	No	O	NA/TC	R (26SEP2020)	N/N
1 1231 12314774	3^	GASTR	Nausea/ Nausea	2	30SEP2020	15/2	2	No	O	NA/TC	R (01OCT2020)	N/N
1 1231 12314790	3^	INFEC	Gingivitis/ Gingivitis	1	03SEP2020	7/8	2	No	O	NA/TC	R (10SEP2020)	N/N
1 1231 12314804												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		VASC	Hypertension/ Arterial Hypertension	1	16SEP2020	20/1	2	No	O	NA/TC	R (16SEP2020)	N/N
		GASTR	Vomiting/ vomits	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
		GENRL	Asthenia/ asthenia	2	03OCT2020	2/2	1	No	O	NA	R (04OCT2020)	N/N
		NERV	Headache/ Headache	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1231 12314813	3^	MUSC	Back pain/ Low back pain	2	21SEP2020	5/22	2	No	O	NA/TC/TCN	R (12OCT2020)	N/N
16-55/ C459100 1 1231 12314816	3^	INJ&P	Ligament injury/ grade 1 injury to the internal collateral ligament of the right knee	2	25SEP2020	10/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1231 12314817	3^	INFEC	Tooth infection/ Dental infection	2	03OCT2020	18/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 1 1231 12314833	3^	INFEC	Appendicitis/ appendicitis	2	16OCT2020	29/9	3	No	O	NA/TC/TCN	R (24OCT2020)	Y/N
		INFEC	Abdominal abscess/ Intra-abdominal Abscess	2	29OCT2020	42/C	3	No	O	NA/TC/TCN	RG	Y/N
16-55/ C459100	3^	NERV	Headache/ headache	2	20OCT2020	35/1	1	No	O	NA	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12314836	3^	SKIN	Rash/ skin rash on chest and neck	2	08OCT2020	23/7	1	No	O	NA/TC	R (14OCT2020)	N/N
1 1231 12314847	3^	GENRL	Fatigue/ Fatigue	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
1 1231 12314852			Injection site pain/ Pain at injection site	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100	3^	MUSC	Neck pain/ Cervicalgia	1	16SEP2020	20/5	1	No	O	NA/TC	R (20SEP2020)	N/N
1 1231 12314857	3^	GASTR	Toothache/ odontogenic pain	2	01OCT2020	16/1	1	No	O	NA/TCN	R (01OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection site pain (left arm)	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
1 1231 12314870		EAR	Vertigo/ Vertigo	2	19SEP2020	2/25	2	No	O	NA/TCN	R (13OCT2020)	N/N
16-55/ C459100		GENRL	Injection site pain/ Pain at the injection site	2	19SEP2020	2/C	1	Yes		NA	RG	N/N
1 1231 12314873												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12314877	3^	INFEC	Oral herpes/ Worsening of herpes labialis	2	23OCT2020	36/10	1	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C459100 1 1231 12314877	3^	GASTR	Toothache/ exacerbation of dental pain	2	04OCT2020	19/6	2	No	O	NA/TC/TCN	R (09OCT2020)	N/N
16-55/ C459100 1 1231 12314878	3^	GENRL	Chills/ INTERMITENT CHILLS	1	05SEP2020	9/10	1	No	O	NA	R (14SEP2020)	N/N
16-55/ C459100 1 1231 12314883	3^	GASTR	Vomiting/ vomiting	1	30AUG2020	3/1	3	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 1 1231 12314885	3^	MUSC	Back pain/ low back pain	2	17OCT2020	32/C	2	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 1 1231 12314889	3^	GENRL	Asthenia/ asthenia	1	05SEP2020	9/1	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C459100 1 1231 12314894	3^	CARD	Myocarditis/ right retroatrial inflammation	2	21SEP2020	6/1	1	No	O	NA/TC	R (21SEP2020)	N/N
16-55/ C459100 1 1231 12314928	3^	GENRL	Pyrexia/ Fever (38.8 degrees C)	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12314931	3^	MUSC	Myalgia/ MYALGIA GENERALIZED	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N
		EYE	Eye allergy/ eye allergy	1	01SEP2020	5/11	1	No	O	NA	R (11SEP2020)	N/N
16-55/ C459100 1 1231 12314935	3^	GENRL	Chest pain/ prechordalgia	1	31AUG2020	4/1	1	No	O	NA/TC	R (31AUG2020)	N/N
16-55/ C459100 1 1231 12314947	3^	GENRL	Asthenia/ asthenia	1	04SEP2020	8/3	1	No	O	NA	R (06SEP2020)	N/N
16-55/ C459100 1 1231 12314974	3^	NERV	Somnolence/ DROWSINESS	1	04SEP2020	8/3	1	No	O	NA	R (06SEP2020)	N/N
		NERV	Headache/ Headache	2	01OCT2020	16/7	1	No	O	NA	R (07OCT2020)	N/N
		BLOOD	Leukopenia/ Leukopenia	2	21OCT2020	36/24	1	No	O	NA	R (13NOV2020)	N/N
16-55/ C459100 1 1231 12314998	3^	INJ&P	Vulvovaginal injury/ Vulvar injury	2	20SEP2020	4/C	1	No	O	NA/TCN	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12315073	3^	INFEC	Bartholinitis/ inflammation of the bartolin glands	2	15OCT2020	29/4	2	No	O	NA/TC/TCN	R (18OCT2020)	N/N
16-55/ C459100 1 1231 12315087	3^	GASTR	Toothache/ toothache	2	10OCT2020	23/1	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1231 12315089	3^	MUSC	Back pain/ low back pain	1	29AUG2020	1/9	1	No	O	NA	R (06SEP2020)	N/N
		MUSC	Back pain/ Low back pain	2	23SEP2020	7/7	2	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C459100 1 1231 12315093	3^	BLOOD	Lymphadenopathy/ Adenopathy in low left cervical region.	2	19SEP2020	3/5	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C459100 1 1231 12315094	3^	MUSC	Neck pain/ Cervicalgia	2	23SEP2020	6/3	2	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1231 12315095	3^	NERV	Paraesthesia/ Paresthesias in both hands	2	29SEP2020	13/45	1	No	O	NA/TC/TCN	R (12NOV2020)	N/N
16-55/ C459100 1 1231 12315101	3^	VASC	Hypertension/ Arterial hypertension	2	19SEP2020	3/1	1	No	O	NA/TC	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		SKIN	Rash maculo-papular/ Maculo psular rash on chest	2	23SEP2020	7/38	1	No	O	NA	R (30OCT2020)	N/N
16-55/ C459100 1 1231 12315167	3^	MUSC	Intervertebral disc protrusion/ DISC PROTRUSION AT CERVICAL LEVEL	2	11OCT2020	25/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 1 1231 12315176	3^	INFEC	Tooth infection/ dental infection	1	10SEP2020	13/4	2	No	O	NA/TC	R (13SEP2020)	N/N
16-55/ C459100 1 1231 12315185	3^	REPRO	Amenorrhoea/ functional amenorrhea	1	16SEP2020	19/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1231 12315186	3^	GASTR	Abdominal pain/ abdominal pain	2	18SEP2020	2/2	3	No	O	NA/TC	R (19SEP2020)	N/N
		MUSC	Myalgia/ abdominal myalgia	2	18SEP2020	2/2	3	No	O	NA/TC	R (19SEP2020)	N/N
		GASTR	Gastritis erosive/ worsening of antral erosive gastritis	2	24SEP2020	8/28	1	No	O	NA/TC/TCN	R (21OCT2020)	N/N
16-55/ C459100 1 1231 12315189	3^	INFEC	Conjunctivitis/ Worsening of rhino conjunctivitis	1	01SEP2020	4/20	1	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chest pain/ prechordalgia	2	03NOV2020	48/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12315190	3^	CARD	Palpitations/ PALPITATIONS	1	04SEP2020	7/6	1	No	O	NA/TCN	R (09SEP2020)	N/N
1 1231 12315201	3^	GENRL	Asthenia/ asthenia	1	30AUG2020	2/5	1	No	O	NA	R (03SEP2020)	N/N
1 1231 12315202		MUSC	Myalgia/ myalgia	1	30AUG2020	2/5	1	No	O	NA	R (03SEP2020)	N/N
			Pain in extremity/ Severe pain in the left upper limb	1	30AUG2020	2/5	3	No	O	NA/TC	R (03SEP2020)	N/N
		MUSC	Arthralgia/ generalized arthralgias	1	17SEP2020	20/7	1	No	O	NA	R (23SEP2020)	N/N
		NERV	Headache/ headache	2	28SEP2020	1/4	2	No	O	NA	R (01OCT2020)	N/N
16-55/ C459100 1 1231 12315204	3^	MUSC	Neck pain/ cervicalgia	1	14SEP2020	17/1	2	No	O	NA/TC/TCN	R (14SEP2020)	N/N
16-55/ C459100 1 1231 12315205	3^	GASTR	Rectal haemorrhage/ Proctorrhagia	2	03OCT2020	17/2	1	No	O	NA	R (04OCT2020)	N/N
16-55/ C459100	3^	SURG	Endodontic procedure/ Endodontic treatment	2	22SEP2020	5/22	1	No	O	NA/TC/TCN	R (13OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12315206	3^	PSYCH	Insomnia/ insomnia	2	22SEP2020	6/43	1	No	O	NA/TC	R (03NOV2020)	N/N
1 1231 12315208	3^	GENRL	Asthenia/ asthenia	1	06SEP2020	9/2	1	No	O	NA	R (07SEP2020)	N/N
1 1231 12315271	3^	GASTR	Lip oedema/ Lip Edema	1	03SEP2020	6/1	1	No	O	NA/TC	R (03SEP2020)	N/N
		SKIN	Pruritus/ perioral pruritus	1	03SEP2020	6/1	1	No	O	NA/TC	R (03SEP2020)	N/N
		GASTR	Lip oedema/ Lip Edema	2	29SEP2020	12/1	1	No	O	NA/TC	R (29SEP2020)	N/N
		SKIN	Pruritus/ perioral pruritus	2	29SEP2020	12/1	1	No	O	NA/TC	R (29SEP2020)	N/N
		MUSC	Muscle spasms/ muscle cramps	2	18OCT2020	31/1	1	No	O	NA/TC	R (18OCT2020)	N/N
		MUSC	Pain in extremity/ pain in left deltoid region	2	28OCT2020	41/C	2	No	O	NA	N	N/N
16-55/ C459100 1 1231 12315280	3^	MUSC	Pain in extremity/ pain in soles and palms	2	25SEP2020	8/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12315286	3^	GENRL	Oedema peripheral/ left foot edema	2	22SEP2020	4/1	1	No	O	NA/TC	R (22SEP2020)	N/N
16-55/ C459100 1 1231 12315287	3^	EYE	Keratitis/ Keratitis	2	29SEP2020	13/16	1	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1231 12315291	3^	EYE	Choroidal neovascularisation/ Myopic choroidal neovascular membrane of the left eye	1	06SEP2020	9/C	2	No	O	NA	N	Y/N
16-55/ C459100 1 1231 12315298	3^	MUSC	Myalgia/ myalgia	2	18SEP2020	2/2	3	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1231 12315299	3^	SKIN	Rash papular/ Erythematous papules in the right malar region	2	20SEP2020	4/52	1	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C459100 1 1231 12315322	3^	NERV	Sciatica/ Worsening of Sciatica	1	16SEP2020	19/1	2	No	O	NA/TC	R (16SEP2020)	N/N
		GENRL	Non-cardiac chest pain/ PRECORDIAL PAIN NON- CARDIAC	1	30SEP2020	33/1	2	No	O	NA	R (30SEP2020)	N/N
16-55/ C459100	3^	VASC	Hot flush/ Hot flushes	2	03OCT2020	16/22	1	No	O	NA	R (24OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12315325	3^	MUSC	Intervertebral disc protrusion/ Incipient disc herniation at L5	2	23SEP2020	7/C	2	No	O	NA/TCN	N	N/N
1 1231 12315349	3^	BLOOD	Lymphadenopathy/ Left axillary adenopathy	2	19SEP2020	3/6	1	No	O	NA	R (24SEP2020)	N/N
1 1231 12315351		MUSC	Arthralgia/ Arthralgias	2	22SEP2020	6/C	2	No	O	NA	N	N/N
16-55/ C459100 1 1231 12315359	3^	INJ&P	Facial bones fracture/ NASAL SEPTUM FRACTURE	1	01SEP2020	4/C	1	No	O	NA/TC	RG	N/N
		REPRO	Amenorrhoea/ amenorrhea	1	16SEP2020	19/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1231 12315362	3^	INFEC	Rash pustular/ pustular rash on the inner right thigh	2	28SEP2020	12/29	1	No	O	NA	R (26OCT2020)	N/N
		GASTR	Abdominal pain upper/ Epigastric pain	2	01OCT2020	15/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1231 12315370	3^	PSYCH	Depression/ Depression	2	05OCT2020	19/36	1	No	O	NA/TC/TCN	R (09NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12315373	3 [^]	GENRL	Chest pain/ Nonspecific chest pain	2	23OCT2020	36/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1231 12315400	3 [^]	EYE	Asthenopia/ Eye fatigue	1	03SEP2020	5/2	1	No	O	NA	R (04SEP2020)	N/N
16-55/ C459100 1 1231 12315401	3 [^]	GENRL	Asthenia/ asthenia	1	03SEP2020	5/3	1	Yes		NA/TC	R (05SEP2020)	N/N
		PSYCH	Depression/ depression	2	25SEP2020	7/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1231 12315412	3 [^]	INV	Alanine aminotransferase increased/ Increased alanine aminotransferase 164 U/l (normal range 15-45 U/l)	2	05NOV2020	48/C	1	No	O	NA	N	N/N
			Aspartate aminotransferase increased/ Increased aspartate aminotransferase 113 U/l (normal range 5-40 U/l)	2	05NOV2020	48/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1231 12315429	3 [^]	GENRL	Injection site pain/ pain at injection site	1	30AUG2020	1/18	2	Yes		P/TC/W	R (16SEP2020)	N/Y
16-55/ C459100	3 [^]	PSYCH	Depression/ depressive syndrome	1	10SEP2020	12/C	3	No	O	P/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12315441												
16-55/ C459100	3^	NERV	Tension headache/ TENSION HEADACHE	1	14SEP2020	16/2	1	No	O	NA	R (15SEP2020)	N/N
1 1231 12315446												
16-55/ C459100	3^	INFEC	Tooth infection/ Left lower wisdom tooth infection	2	09OCT2020	18/8	1	No	O	NA/TCN	R (16OCT2020)	N/N
1 1231 12315450												
		SURG	Wisdom teeth removal/ Dental piece extraction (lower left wisdom tooth)	2	16OCT2020	25/1	1	No	O	NA/TCN	R (16OCT2020)	N/N
16-55/ C459100	3^	REPRO	Mammary duct ectasia/ Breast ductal ectasia	2	07OCT2020	19/33	1	No	O	NA	R (08NOV2020)	N/N
1 1231 12315453												
16-55/ C459100	3^	NERV	Tension headache/ worsening of tensional headache	2	21SEP2020	3/47	1	No	O	NA	R (06NOV2020)	N/N
1 1231 12315460												
16-55/ C459100	3^	GASTR	Odynophagia/ Odynophagia	1	13SEP2020	15/5	1	No	O	NA	R (17SEP2020)	N/N
1 1231 12315464												
		RESP	Rhinorrhoea/ Rhinorrhea	1	13SEP2020	15/5	1	No	O	NA	R (17SEP2020)	N/N
16-55/ C459100	3^	RESP	Rhinitis allergic/ Allergic rhinitis	2	13OCT2020	25/18	1	No	O	NA/TCN	R (30OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12315467	3^	NERV	Headache/ HEADACHE	1	05SEP2020	7/1	1	No	O	NA/TC	R (05SEP2020)	N/N
1 1231 12315470	3^	CARD	Angina unstable/ Unstable Angina Pectoris	2	14OCT2020	26/3	3	No	O	NA/TCN	R (16OCT2020)	Y/N
1 1231 12315473	3^	MUSC	Back pain/ LOW BACK PAIN	1	17SEP2020	19/7	1	No	O	NA/TC	R (23SEP2020)	N/N
1 1231 12315477	3^	GASTR	Neck pain/ CERVICAL PAIN	1	17SEP2020	19/7	1	No	O	NA/TC	R (23SEP2020)	N/N
1 1231 12315497	3^	GASTR	Dyspepsia/ Pyrosis	2	20SEP2020	3/6	1	No	O	NA	R (25SEP2020)	N/N
1 1231 12315499	3^	NERV	Headache/ headache	2	20SEP2020	3/4	2	No	O	NA/TC	R (23SEP2020)	N/N
1 1231 12315499	3^	GENRL	Injection site bruising/ bruise at injection site of left arm	1	30AUG2020	1/18	1	Yes		NA	R (16SEP2020)	N/Y
1 1231 12315499	3^	GASTR	Aphthous ulcer/ Aphthous stomatitis	2	22SEP2020	5/C	1	No	O	NA/TCN	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12315504	3^	NERV	Headache/ headache	1	30AUG2020	1/20	1	No	O	NA/TC	R (18SEP2020)	N/N
1 1231 12315516	3^	RESP	Rhinorrhoea/ rhinorrhea	1	17SEP2020	19/3	1	No	O	NA	R (19SEP2020)	N/N
1 1231 12315518	3^	METAB	Type 2 diabetes mellitus/ Worsening of your type 2 diabetes.	1	17SEP2020	19/2	2	No	O	NA/TC	R (18SEP2020)	N/N
1 1231 12315528	3^	BLOOD	Lymphadenopathy/ Left axillary adenomegaly	2	20SEP2020	2/6	2	No	O	NA/TC	R (25SEP2020)	N/N
1 1231 12315542	3^	GENRL	Asthenia/ Asthenia.	2	16OCT2020	28/8	1	No	O	NA	R (23OCT2020)	N/N
1 1231 12315546	3^	VASC	Hypertension/ Worsening of Hypertension	1	19SEP2020	20/1	1	No	O	NA	R (19SEP2020)	N/N
1 1231 12315547	3^	ENDO	Hyperprolactinaemia/ Hyperprolactinemia	1	15SEP2020	16/C	1	No	CD	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12315559	3^	GASTR	Flatulence/ meteorism (abdominal pain in the left iliac fossa)	2	04OCT2020	14/10	3	No	O	NA/TC	R (13OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	19SEP2020	1/2	2	No	O	NA/TC	R (20SEP2020)	N/N
	3^	MUSC	Myalgia/ generalized myalgia	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
		BLOOD	Lymphadenopathy/ Left axillar adenomegaly	2	20SEP2020	2/7	2	Yes		NA/TC	R (26SEP2020)	N/N
		METAB	Dyslipidaemia/ dyslipidemia	1	17SEP2020	18/21	1	No	O	NA/TC/TCN	R (07OCT2020)	N/N
		MUSC	Back pain/ LOW BACK PAIN	1	13SEP2020	14/1	2	No	O	NA/TC	R (13SEP2020)	N/N
		MUSC	Back pain/ Back pain	1	25OCT2020	56/2	2	No	O	NA/TC	R (26OCT2020)	N/N
		NERV	Sciatica/ Lumbociatalgia	2	15OCT2020	27/12	1	No	O	NA/TC	R (26OCT2020)	N/N
3^	MUSC	Arthralgia/ left omalgia	1	17SEP2020	18/15	1	No	O	NA/TC	R (01OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1231 12315645	3^	MUSC	Myalgia/ Low Back Myalgia	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N
		REPRO	Erectile dysfunction/ FUNCTIONAL IMPOTENCE	1	10SEP2020	11/2	2	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1231 12315681	3^	SURG	Rhinoplasty/ COSMETIC RHINOPLASTY	1	07SEP2020	8/1	2	No	O	NA/TC	RS (07SEP2020)	N/N
		SKIN	Urticaria contact/ generalized contact urticaria	1	03OCT2020	34/16	1	No	O	NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 1232 12321010	3^	GENRL	Pyrexia/ Fever	2	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
		GENRL	Chills/ Chills	2	04SEP2020	3/2	2	Yes		NA	R (05SEP2020)	N/N
		INFEC	Sinusitis/ Sinusitis	2	09SEP2020	8/3	1	No	CND	NA	R (11SEP2020)	N/N
16-55/ C459100 1 1232 12321053	3^	GENRL	Pain/ Body aches	2	11SEP2020	2/4	1			NA	R (14SEP2020)	N/N
			Pyrexia/ Fever	2	11SEP2020	2/4	1			NA	R (14SEP2020)	N/N
		NERV	Headache/ Headache	2	11SEP2020	2/4	1			NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1232 12321086	3^	GENRL	Axillary pain/ Under arm pain	2	12SEP2020	3/2	1			NA	R (13SEP2020)	N/N
			Injection site pain/ Pain in arm at injection site	2	12SEP2020	3/2	1			NA	R (13SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	13SEP2020	4/2	1			NA	R (14SEP2020)	N/N
		GENRL	Asthenia/ Weakness	2	13SEP2020	4/10	1			NA	R (22SEP2020)	N/N
		EYE	Vision blurred/ Blurry vision	2	14SEP2020	5/9	1			NA	R (22SEP2020)	N/N
		NERV	Syncope/ Syncopal*		25AUG2020	1/1	1	No	O	NA	R (25AUG2020)	N/N
		BLOOD	Anaemia/ Worsening Anemia	2	16OCT2020	25/5	1	No	O	NA	R (20OCT2020)	N/N
		REPRO	Vaginal haemorrhage/ abnormal vaginal bleeding	2	19OCT2020	28/1	1	No	O	NA	R (19OCT2020)	N/N
16-55/ C459100 1 1232 12321213	3^	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	01OCT2020	23/C		No	O	P	UNK	N/N
16-55/ C459100 1 1232 12321293	3^	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	1	22OCT2020	22/C		No	O	P	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1235 12351074	3^	INFEC	Conjunctivitis/ Conjunctivitis	2	16OCT2020	11/6	1	Yes		NA/TC	R (21OCT2020)	N/N
			Pharyngitis/ Pharyngitis	2	16OCT2020	11/6	1	Yes		NA/TC	R (21OCT2020)	N/N
		NERV	Headache/ cephalgia	2	16OCT2020	11/6	1	Yes		NA/TC	R (21OCT2020)	N/N
		RESP	Nasal congestion/ Nasal Congestion	2	16OCT2020	11/6	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 1 1235 12351083	3^	GENRL	Chills/ Chills after Vaccine 2	2	07OCT2020	2/4	2	Yes		NA	R (10OCT2020)	N/N
			Fatigue/ Fatigue after Vaccine 2	2	07OCT2020	2/4	2	Yes		NA	R (10OCT2020)	N/N
		MUSC	Pain in extremity/ Left arm pain after Vaccine 2	2	07OCT2020	2/4	2	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1235 12351084	3^	GENRL	Chills/ Rigors	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		NERV	Headache/ Cephalgia	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Rigor	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1235 12351098		NERV	Headache/ Cephalgia	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1235 12351101	3^	GENRL	Pain/ body aches	2	25OCT2020	18/2	1	No	O	NA/TC	R (26OCT2020)	N/N
		RESP	Cough/ cough	2	25OCT2020	18/2	1	No	O	NA/TC	R (26OCT2020)	N/N
			Nasal congestion/ nasal congestion	2	25OCT2020	18/2	1	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C459100 1 1235 12351105	3^	GENRL	Chills/ chills	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
			Pain/ body aches	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
			Pyrexia/ fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		NERV	Headache/ mild headache	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1235 12351110	3^	GENRL	Chills/ chills	2	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N
			Pain/ body aches	2	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1235 12351131	3^	MUSC	Myalgia/ Myalgia, generalized	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1235 12351137	3^	MUSC	Myalgia/ Myalgia	1	15OCT2020	24/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1235 12351143	3^	GENRL	Chills/ chills	2	12OCT2020	1/4	1	Yes		NA/TC	R (15OCT2020)	N/N
			Pyrexia/ pyrexia	2	12OCT2020	1/4	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1241 12411001	3^	GENRL	Injection site pain/ Injection site pain	1	07AUG2020	1/1	1	Yes		NA	R (07AUG2020)	N/Y
		SURG	Dental operation/ Dental surgery	1	20AUG2020	14/1	1	No	O	NA	R (20AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/Y
16-55/ C459100 1 1241 12411002	3^	GENRL	Injection site erythema/ Injection site erythema	1	07AUG2020	1/2	1	Yes		NA	R (08AUG2020)	N/Y
		GENRL	Chills/ Chills	2	26AUG2020	1/1	1	Yes		NA/TC	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411004	3^	MUSC	Pyrexia/ Fever	2	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
			Myalgia/ Myalgia	2	26AUG2020	1/2	2	Yes		NA	R (27AUG2020)	N/N
			Vomiting/ Vomiting	2	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	07AUG2020	1/3	1	Yes		NA	R (09AUG2020)	N/Y
		MUSC	Myalgia/ Myalgia	2	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
		NERV	Headache/ Intermittent Headache	2	26AUG2020	1/2	2	No	O	NA/TC	R (27AUG2020)	N/N
		GENRL	Chills/ Chills	2	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 1 1241 12411005	3^	GASTR	Pyrexia/ Fever	2	27AUG2020	2/2	1	Yes		NA/TC	R (28AUG2020)	N/N
			Nausea/ Nausea	2	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Chills/ Chills	2	26AUG2020	1/3	1	Yes		NA/TC	R (28AUG2020)	N/N
			Injection site pain/ Injection site pain	2	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/Y
				2	26AUG2020	1/1	2	Yes		NA/TC	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411010	3^	NERV	Pyrexia/ Fever	2	26AUG2020	1/3	1	Yes		NA/TC	R (28AUG2020)	N/N
			Headache/ Headache	2	26AUG2020	1/3	1	Yes		NA/TC	R (28AUG2020)	N/N
16-55/ C459100 1 1241 12411010	3^	GENRL	Injection site erythema/ Injection site erythema	1	07AUG2020	1/1	1	Yes		NA	R (07AUG2020)	N/Y
16-55/ C459100 1 1241 12411011	3^	MUSC	Myalgia/ Myalgia	2	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 1 1241 12411013	3^	GENRL	Injection site pain/ Injection site pain	1	10AUG2020	1/3	1	Yes		NA	R (12AUG2020)	N/Y
16-55/ C459100 1 1241 12411014	3^	GENRL	Injection site pain/ Injection site pain	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y
16-55/ C459100 1 1241 12411016	3^	GENRL	Injection site pain/ Injection site pain	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y
16-55/ C459100 1 1241 12411018	3^	RESP	Rhinitis allergic/ Allergic rhinitis	2	21SEP2020	22/1	1	No	O	NA	R (21SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	1	10AUG2020	1/3	1	Yes		NA	R (12AUG2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411019	3^	NERV	Headache/ headache	1	27AUG2020	18/3	1	No	O	NA	R (29AUG2020)	N/N
1 1241 12411020	3^	GENRL	Chills/ Chills	1	12AUG2020	3/2	1	Yes		NA	R (13AUG2020)	N/N
1 1241 12411021	3^	NERV	Headache/ Headache	1	28AUG2020	19/1	1	No	O	NA/TC	R (28AUG2020)	N/N
1 1241 12411022	3^	ENDO	Hypogonadism/ Hypogonadism	1	19AUG2020	10/43	1	No	O	NA/TC	R (30SEP2020)	N/N
		METAB	Dyslipidaemia/ Dyslipidemia	1	19AUG2020	10/C	1	No	O	NA/TC	RG	N/N
1 1241 12411024	3^	NERV	Headache/ Headache	1	26AUG2020	17/1	2	No	O	NA/TC	R (26AUG2020)	N/N
1 1241 12411029	3^	INFECTION	Tonsillitis/ Acute tonsillitis	1	11AUG2020	2/7	1	No	O	NA/TC	R (17AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INFEC	Tonsillitis/ Acute tonsillitis	2	01SEP2020	2/9	1	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C459100 1 1241 12411030	3^	INFEC	Ear infection/ Otitis	1	20AUG2020	11/4	1	No	O	NA/TC	R (23AUG2020)	N/N
16-55/ C459100 1 1241 12411032	3^	NERV	Dysgeusia/ Bitter taste in mouth	1	11AUG2020	1/1	1	Yes		NA	R (11AUG2020)	N/Y
		NERV	Dysgeusia/ Bitter taste in mouth	2	03SEP2020	1/1	1	Yes		NA	R (03SEP2020)	N/Y
16-55/ C459100 1 1241 12411034	3^	SURG	Sclerotherapy/ Sclerotherapy	2	23SEP2020	22/1	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411040	3^	NERV	Headache/ Headache	2	28SEP2020	28/1	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C459100 1 1241 12411044	3^	GENRL	Injection site pain/ Injection site pain	1	11AUG2020	1/1	2	Yes		NA	R (11AUG2020)	N/Y
16-55/ C459100 1 1241 12411045	3^	INFEC	Oral herpes/ Lip herpes	1	18AUG2020	8/5	1	No	O	NA/TC	R (22AUG2020)	N/N
16-55/ C459100	3^	NERV	Headache/ Headache	1	29AUG2020	19/2	2	No	O	NA/TC	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411047	3^	BLOOD	Lymphadenopathy/ Left Axillary lymphadenopathy	2	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N
1 1241 12411051		INFEC	Oral candidiasis/ Oral thrush	2	06SEP2020	5/6	1	Yes		NA	R (11SEP2020)	N/N
		INFEC	Cystitis/ Cystitis	2	07OCT2020	36/8	2	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1241 12411062	3^	NERV	Headache/ Headache	2	22SEP2020	21/3	2	No	O	NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1241 12411070	3^	SURG	Gingival operation/ Gingivoplasty	2	21SEP2020	20/1	1	No	O	NA/TC	R (21SEP2020)	N/N
		VASC	Thrombophlebitis superficial/ Left great saphenous thrombophlebitis	2	12OCT2020	41/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1241 12411072	3^	MUSC	Neck pain/ Cervicalgia	2	01NOV2020	61/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1241 12411093	3^	REPRO	Dysmenorrhoea/ Menstrual cramps	2	30SEP2020	28/3	2	No	O	NA/TC	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411097	3^	MUSC	Myalgia/ Myalgia	1	19AUG2020	7/3	2	Yes		NA/TC	R (21AUG2020)	N/N
16-55/ C459100 1 1241 12411106	3^	INFEC	Otitis media acute/ Acute otitis media	1	21AUG2020	9/10	2	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C459100 1 1241 12411114	3^	INFEC	Vaginal infection/ Colpitis	1	28AUG2020	15/68	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C459100 1 1241 12411125	3^	GENRL	Injection site pain/ Injection site pain	1	14AUG2020	1/2	1	Yes		NA	R (15AUG2020)	N/Y
16-55/ C459100 1 1241 12411132	3^	GENRL	Fatigue/ Intermittent fatigue	1	18OCT2020	66/6	1	No	O	NA	R (23OCT2020)	N/N
16-55/ C459100 1 1241 12411134	3^	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N
		NERV	Headache/ Headache	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100 1 1241 12411135	3^	INFEC	Urinary tract infection/ Urinary tract infection	2	05SEP2020	2/10	2	No	O	NA/TC	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Arthralgia/ Arthralgia	2	05SEP2020	2/8	2	Yes		NA/TC	R (12SEP2020)	N/N
			Myalgia/ Myalgia	2	05SEP2020	2/8	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1241 12411137	3^	GENRL	Injection site pain/ Injection site pain	1	14AUG2020	1/1	1	Yes		NA	R (14AUG2020)	N/Y
16-55/ C459100 1 1241 12411175	3^	INFEC	Folliculitis/ Folliculitis in the left armpit	1	02SEP2020	17/9	1	No	O	NA	R (10SEP2020)	N/N
16-55/ C459100 1 1241 12411197	3^	INJ&P	Ligament sprain/ Left ankle sprain	2	24SEP2020	17/7	2	No	O	NA/TC	R (30SEP2020)	N/N
		INFEC	Tooth infection/ Dental inflammation	2	28SEP2020	21/15	1	No	O	NA/TC	R (12OCT2020)	N/N
16-55/ C459100 1 1241 12411198	3^	INFEC	Fungal skin infection/ Fungal dermatitis	2	10SEP2020	3/C	1	No	O	NA/TC	RG	N/N
		INFEC	Folliculitis/ Folliculitis in the armpits	2	15OCT2020	38/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1241 12411206	3^	REPRO	Breast hyperplasia/ Atypical intraductal hyperplasia in left breast	2	29SEP2020	21/2	2	No	O	NA/TC	R (30SEP2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411214	3^	RESP	Cough/ Cough	2	24SEP2020	16/2	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C459100 1 1241 12411224	3^	IMMUN	Food allergy/ Worsening Allergic reaction to shrimp	1	19AUG2020	2/1	1	No	O	NA/TC	R (19AUG2020)	N/N
16-55/ C459100 1 1241 12411231	3^	NERV	Headache/ Worsening Recurrent headache	2	02OCT2020	23/5	2	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1241 12411236	3^	NERV	Dizziness/ Dizziness	1	08SEP2020	22/2	1	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C459100 1 1241 12411242	3^	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/6	1	Yes		NA	R (14SEP2020)	N/Y
16-55/ C459100 1 1241 12411243	3^	RESP	Rhinitis allergic/ Allergic rhinitis	2	11SEP2020	3/1	1	No	O	NA/TC	R (11SEP2020)	N/N
		REPRO	Dysmenorrhoea/ Menstrual cramps	2	29SEP2020	21/1	1	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C459100 1 1241 12411255	3^	REPRO	Dysmenorrhoea/ Menstrual cramps	1	05SEP2020	19/1	1	No	O	NA/TC	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411261	3^	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/Y
16-55/ C459100 1 1241 12411262	3^	MUSC	Arthritis/ Right knee arthritis	1	06SEP2020	19/21	2	No	O	NA/TC	R (26SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	14SEP2020	1/6	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1241 12411268	3^	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/Y
16-55/ C459100 1 1241 12411270	3^	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
			Pain/ Body pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1241 12411272	3^	NERV	Headache/ Headache	1	19AUG2020	1/3	2	Yes		NA	R (21AUG2020)	N/N
		GENRL	Pyrexia/ Fever	1	20AUG2020	2/2	2	Yes		NA	R (21AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411274	3^	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/4	2	Yes		NA	R (23AUG2020)	N/N
16-55/ C459100 1 1241 12411278	3^	GENRL	Pyrexia/ Fever	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
		GASTR	Abdominal pain/ Abdominal pain	2	12SEP2020	5/1	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1241 12411279	3^	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	10SEP2020	23/35		No	O	P	R (14OCT2020)	N/N
		REPRO	Vaginal haemorrhage/ Vaginal bleeding	1	05OCT2020	48/10	1	No	O	NA/TC	R (14OCT2020)	N/N
		PREG	Retained products of conception/ RETAINED PRODUCTS OF CONCEPTION	1	14OCT2020	57/1	3	No	O	NA/TC	R (14OCT2020)	Y/N
16-55/ C459100 1 1241 12411280	3^	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1241 12411281	3^	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/3	2	Yes		NA	R (22AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411286	3^	IMMUN	Drug hypersensitivity/ Drug allergy	1	10SEP2020	23/1	3	No	CD	NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1241 12411287	3^	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
			Injection site pain/ Injection site pain	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1241 12411290	3^	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
		RESP	Rhinitis allergic/ Headache due to allergic rhinitis	1	20AUG2020	2/2	1	No	O	NA/TC	R (21AUG2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	3/1	1	No	O	NA	R (21AUG2020)	N/N
			Vomiting/ Vomiting	1	21AUG2020	3/1	1	No	O	NA	R (21AUG2020)	N/N
		NERV	Paraesthesia/ Tingling in the left upper limb	1	21AUG2020	3/1	2	Yes		NA	R (21AUG2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C459100	3^	NERV	Migraine/ Migraine crisis	2	07OCT2020	28/12	2	No	O	NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411292	3^	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N
1 1241 12411293	3^	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
1 1241 12411295	3^	REPRO	Dysmenorrhoea/ menstrual cramps*		19AUG2020	1/3	2	No	O	NA/TC	R (21AUG2020)	N/N
1 1241 12411301	3^	GASTR	Nausea/ Nausea	2	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
			Somnolence/ Drowsiness	2	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1241 12411305	3^	GENRL	Chills/ Chills	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411307	3^	GENRL	Pyrexia/ Fever	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1241 12411308	3^	GENRL	Injection site erythema/ Injection site erythema	2	11SEP2020	2/8	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Paraesthesia/ Tingling in the body	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ Headache	1	19AUG2020	1/5	1	Yes		NA/TC	R (23AUG2020)	N/N
16-55/ C459100 1 1241 12411311	3^	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1241 12411312	3^	GENRL	Pyrexia/ Fever	1	20AUG2020	2/1	2	Yes		NA/TC	R (20AUG2020)	N/N
16-55/ C459100 1 1241 12411313	3^	MUSC	Myalgia/ Myalgia	1	20AUG2020	2/1	2	Yes		NA/TC	R (20AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411315	3^	MUSC	Myalgia/ Myalgia	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ Headache	1	06SEP2020	19/1	1	No	O	NA/TC	R (06SEP2020)	N/N
16-55/ C459100 1 1241 12411317	3^	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/Y
16-55/ C459100 1 1241 12411319	3^	INFEC	Varicella/ varicella	1	01SEP2020	14/4	1	No	O	NA/TC	R (04SEP2020)	N/N
		INFEC	Gastroenteritis/ Food gastroenteritis	1	10SEP2020	23/1	1	No	O	NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100 1 1241 12411333	3^	GENRL	Injection site warmth/ Injection site heat	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Injection site pain/ Injection site pain	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411339		GENRL	Chills/ Chills	2	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
			Fatigue/ Fatigue	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
		NERV	Headache/ Headache	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C459100 1 1241 12411342	3^	GENRL	Injection site pain/ Injection site pain	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1241 12411343	3^	GENRL	Injection site pain/ Injection site pain	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
		MUSC	Back pain/ Backache	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N
			Pain in extremity/ Legs pain	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C459100 1 1241 12411344	3^	GENRL	Asthenia/ Asthenia	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ chills	1	20AUG2020	1/1	1	Yes		NA	R (20AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411345		NERV	Headache/ Headache	1	20AUG2020	1/2	1	Yes		NA/TC	R (21AUG2020)	N/N
16-55/ C459100 1 1241 12411347	3^	NERV	Headache/ Headache	1	09SEP2020	21/1	1	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C459100 1 1241 12411348	3^	NERV	Headache/ Headache	1	10SEP2020	22/1	1	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C459100 1 1241 12411356	3^	GENRL	Pyrexia/ Fever	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1241 12411368	3^	GENRL	Chills/ Chills	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
			Fatigue/ Fatigue	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
			Injection site pain/ Injection site pain	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
			Pyrexia/ Fever	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ Headache	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411370	3^	GENRL	Chills/ Chills	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
			Fatigue/ Fatigue	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/N
			Injection site pain/ Injection site pain	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100 1 1241 12411372	3^	NERV	Headache/ Headache	1	04SEP2020	16/1	1	No	O	NA/TC	R (04SEP2020)	N/N
16-55/ C459100 1 1241 12411376	3^	GASTR	Toothache/ Toothache	2	18SEP2020	8/1	1	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1241 12411377	3^	GENRL	Chills/ Chills	2	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
			Injection site pain/ Injection site pain	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
			Pain/ Body pain	2	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
			Pyrexia/ Fever	2	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ headache	2	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411381	3^	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux disease	2	20SEP2020	12/4	1	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411383	3^	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ Fever	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1241 12411384	3^	GENRL	Injection site pain/ Injection site pain	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
			Malaise/ Malaise	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Tension headache/ Tension headache	2	09OCT2020	29/1	1	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1241 12411385	3^	REPRO	Dysmenorrhoea/ dysmenorrhea	1	05SEP2020	17/1	1	No	O	NA/TC/TCN	R (05SEP2020)	N/N
16-55/ C459100 1 1241 12411386	3^	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	1/1	1	Yes		NA	R (20AUG2020)	N/Y
16-55/ C459100 1 1241 12411387	3^	GENRL	Fatigue/ Fatigue	2	16SEP2020	1/3	2	Yes		NA/TCN	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411390	3^	GENRL	Chills/ Chills	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
			Pyrexia/ Fever	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1241 12411390	3^	NERV	Headache/ Headache	1	07SEP2020	19/1	2	No	O	NA/TC	R (07SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1241 12411393	3^	GENRL	Injection site pain/ Injection site pain	1	21AUG2020	1/2	2	Yes		NA/TC	R (22AUG2020)	N/N
16-55/ C459100 1 1241 12411402	3^	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Chills/ Chills	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1241 12411408	3^	MUSC	Fatigue/ Prostration	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
			Injection site pain/ Injection site pain	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
			Myalgia/ Myalgia	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411409	3^	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
			Fatigue/ Prostration	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1241 12411411	3^	GENRL	Injection site pruritus/ Injection site itching	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1241 12411413	3^	GENRL	Chills/ Chills	2	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 1 1241 12411416	3^	GASTR	Nausea/ Nausea	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1241 12411418	3^	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1241 12411423	3^	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411424	3^	NERV	Headache/ Headache	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C459100 1 1241 12411432	3^	INFEC	Vulvovaginal candidiasis/ Vaginal candidiasis	1	07SEP2020	15/21	1	No	O	NA/TC	R (27SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1241 12411435	3^	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y
		NERV	Headache/ Headache	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y
16-55/ C459100 1 1241 12411437	3^	GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1241 12411438	3^	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1241 12411439	3^	GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411443	3^	GENRL	Injection site erythema/ Erythema at the injection site	2	15SEP2020	2/5	2	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ Injection site pain	2	15SEP2020	2/5	2	Yes		NA	R (19SEP2020)	N/N
			Injection site swelling/ Swelling the injection site	2	15SEP2020	2/5	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1241 12411444	3^	NERV	Tension headache/ Tension headache	1	10SEP2020	18/1	1	No	O	NA/TC	R (10SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
		INJ&P	Skin laceration/ Cutting injury in left hand	2	19SEP2020	6/1	2	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1241 12411447	3^	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
			Injection site pain/ Injection site pain	2	14SEP2020	1/1	1	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C459100 1 1241 12411449	3^	NERV	Headache/ headache	2	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1241 12411451	3^	GENRL	Injection site erythema/ Injection site redness	2	15SEP2020	2/3	2	Yes		NA/TCN	R (17SEP2020)	N/N	
			Injection site pain/ Injection site pain	2	15SEP2020	2/3	2	Yes		NA/TCN	R (17SEP2020)	N/N	
			Injection site swelling/ Injection site swelling	2	15SEP2020	2/3	2	Yes		NA/TCN	R (17SEP2020)	N/N	
			Pyrexia/ Fever	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N	
16-55/ C459100 1 1241 12411452	3^	GENRL	Injection site pain/ Injection site pain*		24AUG2020	1/8	2	Yes		NA	R (31AUG2020)	N/N	
			GENRL	Injection site swelling/ Injection site swelling	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N
			MUSC	Myalgia/ Myalgia	1	26AUG2020	3/6	2	Yes		NA	R (31AUG2020)	N/N
			GENRL	Chills/ Chills	1	30AUG2020	7/1	1	Yes		NA	R (30AUG2020)	N/N
			GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/6	2	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C459100 1 1241 12411453	3^	GENRL	Pyrexia/ Fever	2	15SEP2020	2/4	2	Yes		NA/TC	R (18SEP2020)	N/N	
			Injection site pain/ Injection site pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11241 12411456	3^	GASTR	Nausea/ Nausea	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
			Fatigue/ Prostration	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
			Pyrexia/ Fever	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		NERV	Headache/ headache	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C459100 11241 12411461	3^	GASTR	Nausea/ Nausea	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 11241 12411462	3^	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
			Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
			Pyrexia/ Fever	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411464	3^	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y
			Injection site swelling/ Injection site swelling	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y
		GASTR	Abdominal pain/ Abdominal pain	2	14SEP2020	1/5	1	Yes		NA/TC	R (18SEP2020)	N/N
			Diarrhoea/ Diarrhea	2	14SEP2020	1/5	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/Y
16-55/ C459100 1 1241 12411465	3^	METAB	Food intolerance/ Gastrointestinal food intolerance	1	31AUG2020	8/1	1	No	O	NA/TC	R (31AUG2020)	N/N
			GENRL	Chills/ Chills	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)
		Pain/ Body pain		2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
		Pyrexia/ Fever		2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	9/1	2	No	O	NA	R (24SEP2020)	N/N
16-55/ C459100 1 1241 12411466	3^	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11241 12411470	3^	GENRL	Chills/ Chills	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
			Pyrexia/ Fever	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C459100 11241 12411471	3^	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/Y
		GASTR	Nausea/ Nausea	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Chills/ Chills	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
			Fatigue/ Fatigue	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
			Injection site pain/ Injection site pain	2	15SEP2020	1/7	2	Yes		NA/TC	R (21SEP2020)	N/N
			Injection site swelling/ Injection site swelling	2	15SEP2020	1/7	2	Yes		NA/TC	R (21SEP2020)	N/N
			Pyrexia/ Fever	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		BLOOD	Lymphadenopathy/ Reactive axillary lymph node in the left arm	2	16SEP2020	2/11	2	Yes		NA/TC	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11241 12411475	3^	GENRL	Chills/ Chills	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 11241 12411476	3^	NERV	Dizziness/ Dizziness	1	29AUG2020	5/1	1	No	O	NA	R (29AUG2020)	N/N
16-55/ C459100 11241 12411477	3^	NERV	Headache/ Headache	1	25AUG2020	1/1	2	Yes		NA/TC	R (25AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
			Injection site swelling/ Injection site swelling	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
		MUSC	Myalgia/ Myalgia	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
		GENRL	Chills/ Chills	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
			Fatigue/ Fatigue	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ Injection site pain	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411480												
16-55/ C459100 1 1241 12411483	3^	GENRL	Chills/ Chills	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
			Fatigue/ Fatigue	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
			Injection site pain/ Injection site pain	2	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N
			Pain/ Body pain	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
			Pyrexia/ Fever	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1241 12411487	3^	NERV	Tension headache/ Tension headache	1	12SEP2020	19/1	1	No	O	NA/TC	R (12SEP2020)	N/N
16-55/ C459100 1 1241 12411495	3^	GENRL	Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1241 12411497	3^	GENRL	Injection site pain/ Injection site pain	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ Chills	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
			Fatigue/ Fatigue	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
			Pyrexia/ Fever	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C459100 1 1241 12411500	3^	GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1241 12411501	3^	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
			Malaise/ Malaise	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1241 12411502	3^	GENRL	Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1241 12411503	3^	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11241 12411505	3^	GASTR	Nausea/ Nausea	2	16SEP2020	2/3	3	Yes		NA	R (18SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	16SEP2020	2/3	3	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	16SEP2020	2/3	3	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 11241 12411510	3^	NERV	Headache/ Headache	1	10SEP2020	17/1	1	No	O	NA/TC	R (10SEP2020)	N/N
		GENRL	Chills/ Chills	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 11241 12411512	3^	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Vaccination site oedema/ Edema at the vaccine site	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Chills/ Chills	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411513	3^	MUSC	Myalgia/ Myalgia	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
		NERV	Headache/ headache	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411515	3^	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1241 12411516	3^	GENRL	Injection site pain/ Injection site pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1241 12411519	3^	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C459100 1 1241 12411527	3^	GENRL	Pyrexia/ Fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1241 12411528	3^	GENRL	Injection site pain/ Injection site pain	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411530	3^	GENRL	Chills/ Chills	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
			Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
			Injection site pain/ Injection site pain	2	24SEP2020	2/4	2	Yes		NA/TC	R (27SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
			MUSC Myalgia/ Myalgia	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
NERV Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N			
16-55/ C459100 1 1241 12411532	3^	GENRL	Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411535	3^	INFEC	Influenza/ Flu syndrome	1	14SEP2020	13/4	1	No	O	NA	R (17SEP2020)	N/N
16-55/ C459100 1 1241 12411542	3^	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
			Injection site pain/ Injection site pain	1	03SEP2020	2/4	2	Yes		NA/TC	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
		GENRL	Chills/ Chills	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
			Fatigue/ Fatigue	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1241 12411548	3^	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/Y
16-55/ C459100 1 1241 12411556	3^	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
		NERV	Headache/ Headache	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411557	3^	GENRL	Chills/ Chills	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411558	3^	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Fatigue/ Prostration	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411561	3^	GASTR	Diarrhoea/ Diarrhea	2	25SEP2020	4/6	1	Yes		NA/TC	R (30SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	26SEP2020	5/1	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1241 12411564	3^	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		GENRL	Chills/ Chills	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
			Fatigue/ Fatigue	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411565	3^	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1241 12411567	3^	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411568	3^	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	3/1	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1241 12411569	3^	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site erythema/ Injection site redness	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
			Injection site pain/ Injection site pain	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1241 12411570	3^	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
		INFEC	Cystitis/ Cystitis	2	24OCT2020	31/11	1	No	O	NA/TC	R (03NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411572	3^	GENRL	Chills/ Chills	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411574	3^	GASTR	Odynophagia/ Odynophagia	1	03SEP2020	1/1	1	No	O	NA	R (03SEP2020)	N/Y
16-55/ C459100 1 1241 12411575	3^	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411576	3^	EYE	Eye pain/ Pain in the eyes	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Chills/ Chills	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1241 12411578	3^	GENRL	Pyrexia/ Fever	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1241 12411580	3^	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411582	3 [^]	MUSC	Myalgia/ Myalgia	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411583	3 [^]	NERV	Tension headache/ Tension headache	2	21OCT2020	29/1	1	No	O	NA/TCN	R (21OCT2020)	N/N
16-55/ C459100 1 1241 12411586	3 [^]	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/1	2	Yes		NA/TC	R (04SEP2020)	N/N
16-55/ C459100 1 1241 12411589	3 [^]	MUSC	Myalgia/ Myalgia	1	04SEP2020	2/1	2	Yes		NA/TC	R (04SEP2020)	N/N
		INFEC	Tinea cruris/ Ringworm in the inguinal region	1	04SEP2020	2/4	1	No	O	NA/TCN	R (07SEP2020)	N/N
16-55/ C459100	3 [^]	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411595		METAB	Decreased appetite/ Inapetence	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411599	3^	GENRL	Chills/ Chills	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
			Fatigue/ Fatigue	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
			Injection site pain/ Injection site pain	2	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1241 12411600	3^	INFEC	Rhinitis/ Worsening Recurrent rhinitis	1	21SEP2020	19/2	1	No	O	NA/TC	R (22SEP2020)	N/N
16-55/ C459100 1 1241 12411603	3^	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/Y
16-55/ C459100 1 1241 12411607	3^	GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411613	3^	MUSC	Myalgia/ Myalgia	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	26SEP2020	2/4	2	Yes		NA/TC	R (29SEP2020)	N/N
		NERV	Headache/ Headache	2	26SEP2020	2/4	2	Yes		NA/TC	R (29SEP2020)	N/N
		GENRL	Chills/ Chills	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1241 12411616	3^		Injection site pain/ Injection site pain	1	05SEP2020	2/1	2	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
		NERV	Sciatica/ Left sciatic nerve inflammation	2	16OCT2020	24/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1241 12411619	3^	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1241 12411625	3^	GASTR	Diarrhoea/ Diarrhea	1	21SEP2020	18/2	1	No	O	NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411626	3^	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	2/2	2	Yes		NA/TC	R (06SEP2020)	N/N
			Pyrexia/ Fever	1	05SEP2020	2/2	2	Yes		NA/TC/TCN	R (06SEP2020)	N/N
16-55/ C459100 1 1241 12411632	3^	GENRL	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
		NERV	Headache/ Headache	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100 1 1241 12411633	3^	INFEC	Furuncle/ Furunculosis in buttocks	2	07OCT2020	14/8	1	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1241 12411635	3^	NERV	Headache/ Headache	1	20SEP2020	17/2	1	No	O	NA/TC	R (21SEP2020)	N/N
16-55/ C459100 1 1241 12411636	3^	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
			Injection site pruritus/ Injection site itching	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411637	3^	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Somnolence/ Drowsiness	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1241 12411638	3^	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1241 12411639	3^	GENRL	Pyrexia/ Fever	2	26SEP2020	3/1	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100 1 1241 12411640	3^	RESP	Nasal congestion/ Nasal congestion	2	06OCT2020	13/2	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C459100 1 1241 12411641	3^	INJ&P	Skin laceration/ Second left finger cut	2	11OCT2020	19/1	2	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C459100 1 1241 12411645	3^	GENRL	Chills/ Chills	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1241 12411648	3^	GENRL	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
			NERV	Somnolence/ Drowsiness	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
			GENRL	Pyrexia/ Fever	2	25SEP2020	2/1	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 1 1241 12411651	3^	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/Y	
16-55/ C459100 1 1241 12411653	3^	INFEC	Pelvic inflammatory disease/ Pelvic inflammatory disease	1	14SEP2020	11/26	2	No	O	NA/TC	R (09OCT2020)	N/N	
		GENRL	Injection site pain/ Injection site pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N	
		GENRL	Injection site rash/ Injection site macular papular rash	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N	
		NERV	Headache/ Headache	1	08SEP2020	1/2	2	Yes		NA/TC	R (09SEP2020)	N/N	
		GENRL	Injection site pain/ Injection site pain	1	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N	
16-55/ C459100 1 1241 12411654	3^	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11241 12411656	3^	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
			Pyrexia/ Fever	1	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
		NERV	Headache/ Headache	1	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
		GENRL	Asthenia/ Asthenia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ Injection site pain	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 11241 12411658	3^	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 11241 12411663	3^	GENRL	Pyrexia/ Fever	2	01OCT2020	3/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 11241 12411665	3^	NERV	Headache/ Headache	1	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411667		METAB	Decreased appetite/ Hyporexia	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1241 12411672	3^	GASTR	Diarrhoea/ Diarrhea	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
			Vomiting/ Vomiting	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1241 12411674	3^	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		NERV	Headache/ Headache	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1241 12411678	3^	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100	3^	GENRL	Asthenia/ Asthenia	2	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411680			Chills/ Chills	2	05OCT2020	1/4	1	Yes		NA/TC	R (08OCT2020)	N/N
			Pyrexia/ Fever	2	05OCT2020	1/4	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1241 12411681	3^	GENRL	Chills/ Chills	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
			Fatigue/ Fatigue	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
			Injection site pain/ Injection site pain	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
			Pyrexia/ Fever	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1241 12411683	3^	GENRL	Fatigue/ Fatigue	1	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ Injection site pain	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1241 12411685	3^	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ fatigue	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
			Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/Y
		MUSC	Myalgia/ Muscle pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1241 12411690	3^	GENRL	Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1241 12411692	3^	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/Y
16-55/ C459100 1 1241 12411694	3^	GENRL	Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1241 12411696	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1241 12411699	3^	GENRL	Chest discomfort/ Chest discomfort	1	25SEP2020	11/2	1	No	O	NA/TC	R (26SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Myalgia	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1241 12411700	3^	GENRL	Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1241 12411701	3^	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
			Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1241 12411707	3^	NERV	Headache/ headache	2	05OCT2020	1/1	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C459100 1 1241 12411708	3^	INJ&P	Injury/ Injury secondary to trauma	1	04OCT2020	19/23	1	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C459100 1 1241 12411709	3^	GENRL	Pyrexia/ Fever	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1241 12411713	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1241 12411714	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1241 12411715	3^	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/1	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C459100 1 1241 12411716	3^	GENRL	Fatigue/ Fatigue	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ Headache	1	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N
		NERV	Headache/ headache	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1241 12411719	3^	GASTR	Aphthous ulcer/ Oral aphthae	1	17SEP2020	2/4	1	Yes		NA/TC	R (20SEP2020)	N/N
			Diarrhoea/ Diarrhea	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Asthenia/ Asthenia	1	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
			Injection site pain/ Injection site pain	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411725	3^	NERV	Headache/ Headache	1	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Asthenia/ Asthenia	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1241 12411727	3^	SKIN	Rash/ Skin rash	1	16SEP2020	1/4	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 1 1241 12411730	3^	MUSC	Arthralgia/ Arthralgia	1	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	08OCT2020	4/1	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1241 12411731	3^	NERV	Headache/ Headache	2	08OCT2020	4/1	1	Yes		NA/TC	R (08OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
			Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
		NERV	Headache/ Headache	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11241 12411733	3^	MUSC	Back pain/ Backache	2	01NOV2020	27/5	1	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C459100 11241 12411736	3^	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	1/3	2	Yes		NA/TC	R (18SEP2020)	N/N
			Vomiting/ Vomiting	1	16SEP2020	1/3	2	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site swelling/ Injection site swelling	2	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/Y
16-55/ C459100 11241 12411740	3^	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Chills/ Chills	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 11241 12411741	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 11241 12411750	3^	MUSC	Back pain/ Backache	1	21SEP2020	6/4	1	No	O	NA/TC	R (24SEP2020)	N/N
16-55/ C459100 11241 12411756	3^	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11241 12411757	3^	GENRL	Pyrexia/ fever	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 11241 12411758	3^	GENRL	Chills/ Chills	1	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
			Injection site pain/ Injection site pain	1	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	1	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Chills/ Chills	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 11241 12411766	3^	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	1	09OCT2020	24/C		No	O	P	UNK	N/N
16-55/ C459100 11241 12411769	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Chills/ Chills	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
			Fatigue/ Fatigue	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ Fever	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1241 12411771	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 1241 12411774	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411775	3^	GENRL	Fatigue/ Fatigue	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/Y
16-55/ C459100 1 1241 12411777	3^	GASTR	Diarrhoea/ Diarrhea	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1241 12411779	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1241 12411782		GENRL	Pyrexia/ Fever	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N	
		MUSC	Myalgia/ Myalgia	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N	
		NERV	Headache/ Headache	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N	
		3^	GENRL	Pyrexia/ Fever	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
		3^	GENRL	Injection site pain/ Injection site pain	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
		3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/3	1	Yes		NA/TCN	R (18SEP2020)	N/N
			GENRL	Pyrexia/ Fever	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
			IMMUN	Drug hypersensitivity/ Allergic reaction to dipyrone	1	17SEP2020	2/1	3	No	CD	NA/TC	R (17SEP2020)	N/N
			GENRL	Injection site pain/ Injection site pain	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411790	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411793	3^	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
			Pyrexia/ Fever	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
			Injection site pain/ Injection site pain	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1241 12411797	3^	GENRL	Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
			Fatigue/ Fatigue	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1241 12411799	3^	GENRL	Chills/ Chills	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
			Pyrexia/ Fever	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
			Chills/ Chills	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
			Fatigue/ Fatigue	1	17SEP2020	1/1	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100	3^	GENRL	Headache/ Headache	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
			Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411800	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
1 1241 12411803		GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
			Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
			Injection site pain/ Injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1241 12411805	3^	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411807	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ Headache	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1241 12411812	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411813	3^	NERV	Headache/ Headache	1	18SEP2020	2/2	3	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
			Pain/ Body pain	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
			Pyrexia/ Fever	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		NERV	Headache/ Headache	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	1	17SEP2020	1/1	1	Yes		NA/TC	R (17SEP2020)	N/N
			NERV	Headache/ Headache	1	17SEP2020	1/1	1	Yes		NA/TC	R (17SEP2020)
16-55/ C459100 1 1241 12411814	3^	MUSC	Myalgia/ Myalgia	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
		NERV	Headache/ Headache	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
		INJ&P	Limb injury/ Right foot trauma	1	05OCT2020	19/14	1	No	O	NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 1241 12411817	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ Chills	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Fatigue/ Fatigue	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	1	18SEP2020	2/2	2	Yes		NA/TC	R (19SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
		GENRL	Asthenia/ Asthenia	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
			Chills/ Chills	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
			Pyrexia/ Fever	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	09OCT2020	2/12	2	Yes		NA	R (20OCT2020)	N/N
		NERV	Headache/ Headache	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411818	3^	GENRL	Pyrexia/ fever	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1241 12411824	3^	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
			Injection site pain/ Injection site pain	2	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ Fever	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411828	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1241 12411830	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1241 12411834	3^	GENRL	Injection site pain/ injection site pain	1	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Fatigue/ Prostration	2	09OCT2020	2/3	2	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1241 12411837	3^	GENRL	Chills/ Chills	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
		MUSC	Fatigue/ Fatigue	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	1	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411839			Injection site pain/ Injection site pain	1	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
			Pyrexia/ Fever	1	18SEP2020	2/2	1	Yes		NA/TC/TCN	R (19SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411845	3^	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1241 12411849	3^	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
			Pyrexia/ Fever	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411850	3^	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ Injection site pain	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ Headache	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411854	3^	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
		NERV	Headache/ Headache	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/5	1	Yes		NA/TCN	R (21SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	1	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1241 12411856	3^	MUSC	Myalgia/ Myalgia	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ Headache	1	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site bruising/ Injection site bruise	2	09OCT2020	1/5	2	Yes		NA	R (13OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	09OCT2020	1/5	2	Yes		NA	R (13OCT2020)	N/N
		GASTR	Nausea/ Nausea	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
		GENRL	Chills/ Chills	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411857	3^	NERV GENRL	Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
			Headache/ Headache	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
			Fatigue/ Prostration	2	09OCT2020	2/1	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1241 12411861	3^	GENRL	Pyrexia/ Fever	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
			Chills/ Chills	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1241 12411862	3^	NERV	Pyrexia/ Fever	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Headache/ Headache	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411862	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		BLOOD	Lymphadenopathy/ Axillary lymph nodes enlargement in left arm	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1241 12411863	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1241 12411866	3^	NERV	Headache/ Headache	1	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/Y
16-55/ C459100 1 1241 12411869	3^	GENRL	Chills/ chills	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1241 12411872	3^	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
			Pyrexia/ Fever	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411875												
16-55/ C459100 1 1241 12411877	3^	GENRL	Asthenia/ Asthenia	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ Injection site pain and burning sensation	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/Y
16-55/ C459100 1 1241 12411879	3^	GENRL	Chills/ Chills	2	09OCT2020	1/1	1	Yes		NA	R (09OCT2020)	N/N
			Injection site pain/ Injection site pain	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411882	3^	GENRL	Chills/ Chills	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
			Fatigue/ Fatigue	2	09OCT2020	1/3	1	Yes		NA/TC	R (11OCT2020)	N/N
			Injection site pain/ Injection site pain	2	09OCT2020	1/3	1	Yes		NA/TC	R (11OCT2020)	N/N
			Pyrexia/ Fever	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411884	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411886	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Asthenia/ Asthenia	1	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
			Pyrexia/ Fever	1	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Fatigue/ Prostration	2	10OCT2020	2/1	2	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411888	3^	GENRL	Fatigue/ Fatigue	1	19SEP2020	2/3	1	Yes		NA/TC	R (21SEP2020)	N/N
			Injection site pain/ Injection site pain	1	19SEP2020	2/3	1	Yes		NA/TC	R (21SEP2020)	N/N
		NERV	Headache/ Headache	1	19SEP2020	2/3	1	Yes		NA/TC	R (21SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
		NERV	Headache/ Headache	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411889	3^	GENRL	Chills/ Chills	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ Injection site pain	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411893	3^	GENRL	Fatigue/ Fatigue	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Asthenia/ Asthenia	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ Injection site pain	1	18SEP2020	1/5	2	Yes		NA	R (22SEP2020)	N/N
		GENRL	Chills/ Chills	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
			Fatigue/ Fatigue	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
			Injection site pain/ Injection site pain	2	09OCT2020	1/3	1	Yes		NA/TC	R (11OCT2020)	N/N
			Pyrexia/ Fever	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411895	3^	NERV	Headache/ Headache	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
		GENRL	Fatigue/ Prostration	2	16OCT2020	3/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1241 12411898	3^	RESP	Rhinorrhoea/ Rhinorrhea	1	07OCT2020	20/2	1	No	O	NA/TC	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411899	3^	GENRL	Chills/ Chills	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
			Pyrexia/ Fever	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411904	3^	GENRL	Chills/ Chills	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
			Fatigue/ Fatigue	2	10OCT2020	2/6	2	Yes		NA	R (15OCT2020)	N/N
			Fatigue/ Prostration	2	10OCT2020	2/6	2	Yes		NA	R (15OCT2020)	N/N
			Injection site pain/ Injection site pain	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C459100 1 1241 12411914	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
			Chills/ Chills	1	22SEP2020	5/4	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	22SEP2020	5/4	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	1	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411920		NERV	Headache/ Headache	1	19SEP2020	2/1	1	Yes		NA/TC/TCN	R (19SEP2020)	N/N
		GENRL	Chills/ chills	2	09OCT2020	1/1	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1241 12411921	3^	GENRL	Injection site erythema/ Injection site redness	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
		NERV	Headache/ Headache	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1241 12411924	3^	GENRL	Pyrexia/ Fever	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	2	Yes		NA/TCN	R (10OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	10OCT2020	2/1	2	Yes		NA/TCN	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411927	3^	GENRL	Chills/ Chills	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
			Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C459100 1 1241 12411931	3^	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1241 12411936	3^	GENRL	Axillary pain/ Left armpit pain	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
			Injection site pain/ Injection site pain	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ Headache	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1241 12411937	3^	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
		NERV	Headache/ Headache	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	3/3	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1241 12411942	3^	GENRL	Pyrexia/ fever	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411943			Injection site pain/ Injection site pain	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1241 12411944	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/Y
16-55/ C459100 1 1241 12411945	3^	GENRL	Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C459100 1 1241 12411948	3^	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
			Injection site swelling/ Injection site swelling	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411950	3^	GENRL	Asthenia/ Asthenia	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
			Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
			Pyrexia/ Fever	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1241 12411951	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
		GENRL	Chills/ Chill	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
		NERV	Headache/ Headache	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1241 12411952	3^	INFEC	Helicobacter gastritis/ Helicobacter pylori gastritis	2	13OCT2020	7/25	1	No	O	NA/TC	R (06NOV2020)	N/N
16-55/ C459100 1 1241 12411956	3^	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1241 12411957	3^	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1241 12411961	3^	GENRL	Fatigue/ Prostration	2	08OCT2020	2/1	2	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1241 12411962	3^	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11241 12411965	3^	MUSC	Myalgia/ Myalgia	1	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N
		NERV	Headache/ Headache	1	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N
		RESP	Nasal obstruction/ Nasal obstruction	1	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
			Rhinorrhoea/ Runny nose	1	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N
		GASTR	Vomiting/ Vomiting due to medication	1	25SEP2020	5/2	1	No	CD	NA	R (26SEP2020)	N/N
16-55/ C459100 11241 12411967	3^	MUSC	Back pain/ Backache (Exacerbation of pre-existing condition)	1	25SEP2020	5/9	2	No	O	NA/TC	R (03OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ Headache	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N
			Injection site pain/ Injection site pain	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N
		NERV	Headache/ Headache	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411970	3^	BLOOD	Lymphadenopathy/ Reactional Left axillary lymph node	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12411972	3^	GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		NERV	Headache/ Headache	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
		GASTR	Nausea/ Nausea	1	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Vomiting/ Vomiting	1	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1241 12411974	3^	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ Headache	1	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
			Pyrexia/ Fever	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1241 12411978	3^	GENRL	Injection site pain/ Injection site pain	1	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ Headache	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1241 12411982	3^	GENRL	Fatigue/ Fatigue	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
			Pyrexia/ Fever	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1241 12411983	3^	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1241 12411984	3^	GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12411988	3^	GENRL	Pyrexia/ Fever	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C459100 1 1241 12411990	3^	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1241 12411993	3^	GENRL	Fatigue/ Prostration	1	21SEP2020	1/1	2	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1241 12411994	3^	GENRL	Pyrexia/ Fever Fatigue/ Fatigue	1	21SEP2020 22SEP2020	1/1 2/1	2 1	Yes Yes		NA NA	R (21SEP2020) R (22SEP2020)	N/N N/N
		NERV	Headache/ Headache	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		NERV	Headache/ Headache	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1241 12411996	3^	GENRL	Injection site pain/ Injection site pain	1	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11241 12412002	3^	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/Y
			Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/Y
		NERV	Headache/ Headache	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/Y
16-55/ C459100 11241 12412004	3^	GENRL	Injection site pain/ Injection site pain	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 11241 12412008	3^	MUSC	Myalgia/ Myalgia	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	14OCT2020	2/3	2	Yes		NA/TC	R (16OCT2020)	N/N
			Pyrexia/ Fever	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	14OCT2020	2/3	2	Yes		NA/TC	R (16OCT2020)	N/N
		NERV	Headache/ Headache	2	14OCT2020	2/3	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100	3^	GENRL	Pain/ Body pain	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12412009		MUSC	Myalgia/ Myalgia	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1241 12412010	3^	SKIN	Skin lesion/ Hypochromic skin lesions	1	30SEP2020	10/21	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412013	3^	GASTR	Nausea/ Nausea	1	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	1	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Headache/ Headache	1	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1241 12412020	3^	GENRL	Injection site pain/ Injection Site pain	1	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1241 12412028	3^	GENRL	Fatigue/ Fatigue	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ Injection site pain	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12412029	3^	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1241 12412032	3^	SKIN	Pruritus/ Itching in the body	1	02OCT2020	3/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1241 12412034	3^	GENRL	Injection site pain/ Injection site pain	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1241 12412035	3^	GASTR	Odynophagia/ Odinophagy	1	13OCT2020	14/4	1	No	O	NA	R (16OCT2020)	N/N
16-55/ C459100 1 1241 12412037	3^	GASTR	Nausea/ Nausea	1	30SEP2020	1/3	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1241 12412043	3^	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1241 12412048	3^	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	1	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12412056			Injection site pain/ Injection site pain	1	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ Headache	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		GASTR	Toothache/ Toothache	1	02OCT2020	3/1	1	No	O	NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1241 12412060	3^	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/Y
16-55/ C459100 1 1241 12412062	3^	GENRL	Injection site pain/ Injection site pain	1	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1241 12412067	3^	GENRL	Injection site pain/ Injection site burning	1	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1241 12412070	3^	GENRL	Injection site pain/ Injection site pain	1	01OCT2020	1/4	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1241 12412071	3^	NERV	Headache/ Headache	1	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1241 12412078	3^	GENRL	Injection site pain/ Injection site pain	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1241 12412084	3^	NERV	Headache/ Headache	1	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1241 12412094	3^	NERV	Headache/ Headache	1	03OCT2020	3/3	1	Yes		NA/TC	R (05OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	06OCT2020	6/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1241 12412100	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	20OCT2020	20/9	2	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C459100 1 1241 12412102	3^	GENRL	Asthenia/ Asthenia	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
			Injection site pain/ Injection site pain	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12412104	3^	GENRL	Fatigue/ Fatigue	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1241 12412105	3^	GENRL	Injection site pain/ Injection site pain	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1241 12412107	3^	GASTR	Dyspepsia/ Dyspepsia	1	20OCT2020	19/1	1	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412110	3^	GENRL	Injection site pain/ Injection site pain	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1241 12412111	3^	NERV	Headache/ Headache	1	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1241 12412112	3^	GENRL	Fatigue/ Fatigue	1	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
			Injection site pain/ Injection site pain	1	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		GENRL	Pyrexia/ Fever	1	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
		NERV	Headache/ Headache	1	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12412117	3^	GENRL	Injection site pain/ Injection site pain	1	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1241 12412121	3^	GENRL	Injection site pain/ Injection site pain	1	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 1 1241 12412135	3^	GENRL	Pain/ Body pain	1	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
			Pyrexia/ Fever	1	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 1241 12412137	3^	GENRL	Injection site pain/ Injection site pain	1	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1241 12412138	3^	GENRL	Chills/ Chills	1	07OCT2020	3/1	1	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ Feeling of fever	1	07OCT2020	3/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100 1 1241 12412139	3^	GENRL	Injection site pain/ Injection site pain	1	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12412140	3^	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
1 1241 12412141	3^	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
1 1241 12412143	3^	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/3	2	Yes		NA	R (09OCT2020)	N/N
1 1241 12412149	3^	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/4	2	Yes		NA	R (10OCT2020)	N/N
1 1241 12412151	3^	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
1 1241 12412152	3^	GENRL	Injection site pain/ Injection site pain	1	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
1 1241 12412155	3^	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/3	1	Yes		NA/TC	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12412160	3^	NERV	Headache/ Headache	1	09OCT2020	3/1	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1241 12412162	3^	SURG	Dental implantation/ Dental implant unit 44	1	28OCT2020	22/1	1	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C459100 1 1241 12412165	3^	GENRL	Injection site pain/ Injection site pain	1	09OCT2020	1/3	2	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1246 12461008	3^	MUSC	Muscle spasms/ Back Muscle Spasm	2	11NOV2020	27/C	2	No	CD	NA/TC	N	N/N
16-55/ C459100 1 1246 12461010	3^	INFEC	Sinusitis/ Sinusitis	1	12OCT2020	18/6	1	No	O	NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 1246 12461025	3^	SKIN	Urticaria/ urticaria generalized	1	29SEP2020	2/4	3	Yes		NA/TC	R (02OCT2020)	N/N
		SKIN	Urticaria/ Intermittent urticaria generalised.	1	07OCT2020	10/27	2	Yes		P/TC	R (02NOV2020)	N/N
16-55/ C459100 1 1246 12461026	3^	INFEC	Sinusitis/ Sinusitis	2	27OCT2020	9/15	2	No	CD	NA/TC	R (10NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1246 12461088	3^	GASTR	Constipation/ Constipation	1	08OCT2020	3/20	2	No	O	NA/TC	R (27OCT2020)	N/N
16-55/ C459100 1 1247 12471016	3^	INFEC	Vaginal infection/ Vaginitis	1	12OCT2020	19/11	2	No	O	NA	R (22OCT2020)	N/N
16-55/ C459100 1 1247 12471019	3^	INFEC	Tinea versicolour/ Tinea Versicolor (upper limbs)	2	28OCT2020	14/C	2	No	O	NA	RG	N/N
16-55/ C459100 1 1247 12471040	3^	INFEC	Blister infected/ Infected Fever Blister	2	10NOV2020	27/3	2	No	O	NA/TC	R (12NOV2020)	N/N
16-55/ C459100 1 1247 12471053	3^	INFEC	Nasopharyngitis/ Common cold	1	08OCT2020	14/3	1	No	O	NA	R (10OCT2020)	N/N
16-55/ C459100 1 1247 12471089	3^	RESP	Allergic sinusitis/ Allergic Sinusitis	1	01OCT2020	3/5	2	No	O	NA/TC	R (05OCT2020)	N/N
16-55/ C459100 1 1247 12471092	3^	INFEC	Escherichia urinary tract infection/ Acute E.coli UTI	1	18OCT2020	20/8	2	No	O	NA/TC	R (25OCT2020)	N/N
16-55/ C459100	3^	INJ&P	Flail chest/ Flail Chest	2	30OCT2020	10/15	3	No	O	NA/TC/TCN/ W	R (13NOV2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1247 12471121			Road traffic accident/ Motorcycle accident	2	30OCT2020	10/1	4	No	O	NA	R (30OCT2020)	N/N
16-55/ C459100 1 1247 12471142	3^	INFEC	Escherichia urinary tract infection/ Uncomplicated E.coli urinary tract infection	1	12OCT2020	12/15	1	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C459100 1 1247 12471147	3^	VASC	Hypertension/ Exacerbation of hypertension	1	13OCT2020	13/10	1	No	O	NA/TC	R (22OCT2020)	N/N
16-55/ C459100 1 1247 12471168	3^	GENRL	Chest pain/ Chest pain	2	12NOV2020	18/2	1	No	O	NA	R (13NOV2020)	N/N
16-55/ C459100 1 1247 12471184	3^	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/9	2	Yes		NA	R (14OCT2020)	N/N
			Injection site pain/ Local injection site pain	1	06OCT2020	1/3	2	Yes		NA	R (08OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain-general	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1247 12471185	3^	GENRL	Injection site pain/ Injection site pain	2	27OCT2020	1/3	2	Yes		NA	R (29OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1247 12471196	3^	GENRL	Pyrexia/ Fever	2	27OCT2020	1/3	2	Yes		NA	R (29OCT2020)	N/N	
			NERV	Headache/ Headache	2	27OCT2020	1/3	3	Yes		NA	R (29OCT2020)	N/N
				Injection site pain/ Local injection pain	1	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
			GASTR	Nausea/ Nausea	1	08OCT2020	3/5	1	Yes		NA	R (12OCT2020)	N/N
			NERV	Headache/ Headache	1	08OCT2020	3/5	1	Yes		NA	R (12OCT2020)	N/N
			MUSC	Arthralgia/ Joint pain	1	10OCT2020	5/5	2	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1247 12471197	3^	GENRL	MUSC	Myalgia/ Muscle pain Generalised	1	11OCT2020	6/4	1	Yes	NA	R (14OCT2020)	N/N	
				Fatigue/ Fatigue	1	07OCT2020	2/7	2	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1247 12471199	3^	GENRL	NERV	Headache/ Headache	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
				Fatigue/ Fatigue	1	06OCT2020	1/1	2	Yes		NA	R (06OCT2020)	N/N
				Injection site erythema/ Injection site redness	1	06OCT2020	1/2	3	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1247 12471222	3^	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/2	2	Yes		NA	R (07OCT2020)	N/N
			Injection site swelling/ Injection site swelling	1	06OCT2020	1/1	3	Yes		NA	R (06OCT2020)	N/N
			Chills/ Chills	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
			Injection site pain/ Injection site pain	1	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C459100 1 1247 12471232	3^	MUSC	Myalgia/ New muscle pain (general)	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ Headache	1	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1248 12481001	3^	GENRL	Chills/ Chills	2	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1248 12481005	3^	EYE	Pyrexia/ Fever	2	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
			Photophobia/ Light Sensitivity (Eyes)	1	29AUG2020	4/5	1	Yes		NA	R (02SEP2020)	N/N
		INFEC	Ear infection/ Right Ear Infection	1	29AUG2020	4/1	2	No	O	NA/TC	R (29AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		EAR	Vertigo/ Vertigo	1	30AUG2020	5/4	1	No	O	NA	R (02SEP2020)	N/N
16-55/ C459100 1 1248 12481012	3^	INJ&P	Foot fracture/ Right Foot Fracture	2	28SEP2020	12/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1248 12481017	3^	GENRL	Injection site pain/ Local Soreness at Injection Site Left Arm	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 1 1248 12481019	3^	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1248 12481023	3^	GASTR	Pyrexia/ Fever Diarrhoea/ Diarrhea	1	30AUG2020	3/1	1	No	O	NA	R (30AUG2020)	N/N
		RESP	Cough/ Cough	1	01SEP2020	5/4	1	Yes		NA/TC	R (04SEP2020)	N/N
		SKIN	Hyperhidrosis/ Sweats	1	01SEP2020	5/4	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1248 12481038	3^	GENRL	Injection site pain/ Left Arm Pain Injection Site	1	30AUG2020	1/4	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1248 12481054	3^	GENRL	Injection site pain/ Injection Site Reaction Pain*		31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C459100 1 1248 12481056	3^	GENRL	Chest pain/ Chest Pain	1	12SEP2020	12/2	1	No	O	NA	R (13SEP2020)	N/N
16-55/ C459100 1 1248 12481061	3^	NERV	Dizziness/ Light-headedness	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y
16-55/ C459100 1 1248 12481065	3^	GASTR	Abdominal pain upper/ Stomachache	1	07SEP2020	4/3	1	No	O	NA	R (09SEP2020)	N/N
			Diarrhoea/ Diarrhea	1	07SEP2020	4/3	1	No	O	NA	R (09SEP2020)	N/N
		INFEC	Tooth abscess/ Abscess (tooth)	2	07OCT2020	14/7	2	No	O	NA/TC/TCN	R (13OCT2020)	N/N
16-55/ C459100 1 1248 12481068	3^	GENRL	Fatigue/ Tiredness	1	05SEP2020	1/3	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C459100 1 1248 12481075	3^	GENRL	Fatigue/ Mild Fatigue	1	05SEP2020	1/1	1	Yes		NA	RS (05SEP2020)	N/N
		MUSC	Myalgia/ Generalized Mild Muscle Aches	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1248 12481076	3^	GENRL	Influenza like illness/ Flu Like Symptoms	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C459100 1 1248 12481077	3^	GENRL	Injection site pain/ Pain Injection Site	1	05SEP2020	1/2	2	Yes		NA	R (06SEP2020)	N/N
		GENRL	Pyrexia/ Fever	1	06SEP2020	2/2	2	Yes		NA	R (07SEP2020)	N/N
		MUSC	Myalgia/ Muscle Ache	1	06SEP2020	2/1	2	Yes		NA	R (06SEP2020)	N/N
		NERV	Headache/ Headache Mild	1	06SEP2020	2/1	2	Yes		NA	R (06SEP2020)	N/N
16-55/ C459100 1 1248 12481081	3^	GENRL	Injection site pain/ Injection site Reaction (Pain)	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C459100 1 1248 12481098	3^	NERV	Headache/ Headache	1	20SEP2020	13/5	1	No	O	NA	R (24SEP2020)	N/N
16-55/ C459100 1 1248 12481103	3^	GENRL	Pyrexia/ Fever Temperature (Unknown Temperature)	1	08SEP2020	1/3	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C459100 1 1248 12481121	3^	UNC	VOMITING@@/ Vomiting	2	13OCT2020	2/2					(14OCT2020)	/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1248 12481123	3^	INJ&P	Procedural pain/ Tooth Ache (after root canal procedure)	1	01OCT2020	20/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1248 12481131	3^	GENRL	Chills/ Chills	1	12SEP2020	1/1	1	Yes		NA	R (12SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	17SEP2020	6/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1248 12481145	3^	GENRL	Injection site pain/ Injection site Reaction (mild pain right upper arm)	1	13SEP2020	1/3	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1248 12481146	3^	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	2/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1248 12481158	3^	GENRL	Injection site pain/ Injection Site Reaction Pain	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Lethargy/ Lethargy	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C459100 1 1248 12481159	3^	GENRL	Chills/ Chills	1	16SEP2020	3/15	1	Yes		NA	R (30SEP2020)	N/N
			Fatigue/ Fatigue	1	16SEP2020	3/21	2	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1248 12481176	3^	GENRL	Pain/ Body Aches	1	19SEP2020	5/2	2	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ Headache	1	19SEP2020	5/2	3	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1248 12481187	3^	GENRL	Injection site pain/ Injection Site Reaction Pain	1	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ Headache	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	08OCT2020	2/1	2	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1248 12481188	3^	GENRL	Injection site pain/ Injection Site Reaction Pain	1	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1248 12481193	3^	GENRL	Influenza like illness/ Flu-Like Symptoms	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 1 1248 12481194	3^	MUSC	Myalgia/ Muscle Aches	1	17SEP2020	1/17	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1248 12481195	3^	GENRL	Exercise tolerance decreased/ Mild Decrease in Exercise Tolerance	1	17SEP2020	1/21	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1248 12481205	3^	GENRL	Fatigue/ Tiredness	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
		MUSC	Pain in extremity/ Left Arm Pain	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100 1 1248 12481212	3^	GASTR	Nausea/ Nausea	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
		PSYCH	Disorientation/ disoriented	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1248 12481213	3^	SKIN	Rash/ Skin Rash on Face and Abdomen	1	20SEP2020	3/5	1	No	O	NA	R (24SEP2020)	N/N
16-55/ C459100 1 1248 12481218	3^	GASTR	Vomiting/ Vomiting*		20SEP2020	/2	1	No	O	NA/TCN	R (21SEP2020)	N/N
		NERV	Syncope/ vasovagal syncope*		20SEP2020	/1	2	No	O	NA/W	R (20SEP2020)	N/N
16-55/ C459100 1 1251 12511046	3^	GENRL	Injection site pain/ upper left arm pain at injection site	1	14SEP2020	22/C	1	Yes		NA/TC	N	N/N
16-55/ C459100 1 1251 12511058	3^	INFEC	Otitis externa/ swimmers ear Left	1	08SEP2020	14/5	1	No	O	NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1251 12511060	3^	RESP	Nasal congestion/ Nasal Congestion	1	02SEP2020	8/3	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1251 12511081	3^	RESP	Sinus congestion/ sinus congestion/wheezing	1	30SEP2020	31/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1251 12511093	3^	GASTR	Diarrhoea/ Diarrhea	1	05SEP2020	5/1	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1251 12511124	3^	NERV	Headache/ headache intermittent	2	12OCT2020	18/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1251 12511127	3^	MUSC	Plantar fasciitis/ Plantar Fasciitis	2	09OCT2020	11/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1251 12511131	3^	REPRO	Ovarian cyst/ ovarian cyst	1	10SEP2020	3/C	2	No	O	NA	N	N/N
16-55/ C459100 1 1251 12511141	3^	GENRL	Chills/ Chills	2	30SEP2020	1/1	1	Yes		NA/TC	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1251 12511155	3^	GENRL	Injection site pain/ Pain at Injection Site Left Deltoid	2	30SEP2020	1/11	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1251 12511161	3^	GENRL	Chills/ Chills	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ Fever	2	07OCT2020	1/3	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 1251 12511171	3^	MUSC	Myalgia/ Muscle Aches (Body)	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1251 12511191	3^	GENRL	Pain/ body aches	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N
			Pyrexia/ fever of 101.4	2	14OCT2020	1/2	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 1251 12511212	3^	GENRL	Pyrexia/ Fever 100.5	1	03OCT2020	10/2	1	Yes		NA/TCN	R (04OCT2020)	N/N
16-55/ C459100 1 1251 12511218	3^	GENRL	Pyrexia/ Fever greater than 100.4 (101.8)	2	15OCT2020	2/1	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Muscle Pain at Injection Site	1	30SEP2020	2/4	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1251 12511221		UNC	INTERMITTENT MUSCLE PAIN LEFT DELTOID@@/ Intermittent Muscle Pain Left Deltoid	2	19OCT2020	1/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1251 12511223	3^	MUSC	Muscle discomfort/ Intermittent Muscle Discomfort Right Upper Arm	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/Y
16-55/ C459100 1 1251 12511233	3^	GENRL	Fatigue/ fatigue	1	10OCT2020	4/5	1	Yes		NA	R (14OCT2020)	N/N
		RESP	Nasal congestion/ nasal congestion	1	10OCT2020	4/5	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1254 12541005	3^	GENRL	Injection site pain/ Soreness at the injection site	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C459100 1 1254 12541027	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	29AUG2020	1/2	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C459100 1 1254 12541030	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	29AUG2020	1/2	1	Yes		NA	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541033	3^	GASTR	Diarrhoea/ DIARRHEA	2	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	19SEP2020	1/3	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Pain/ BODYACHE	2	20SEP2020	2/2	1	Yes		NA/TC	R (21SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	20SEP2020	2/2	1	Yes		NA/TC	R (21SEP2020)	N/N
		NERV	Headache/ headache	1	30AUG2020	2/2	2	Yes		NA	R (31AUG2020)	N/N
		GENRL	Chills/ CHILLS	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Pyrexia/ FEVER TEMPERATURE AT 101.5F	2	20SEP2020	2/1	1	Yes		NA/TC	R (20SEP2020)	N/N
		GENRL	Pyrexia/ FEVER OF 100.9F	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1254 12541038	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	30AUG2020	2/2	1	Yes		NA	R (31AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541039	3^	GENRL	Chills/ CHILLS	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ pain at injection site	2	20SEP2020	2/3	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	03SEP2020	6/3	2	No	O	NA	R (05SEP2020)	N/N
		RESP	Pleuritic pain/ lungs burning sensation	1	12SEP2020	15/1	1	No	O	NA	R (12SEP2020)	N/N
		INV	Body temperature increased/ Elevated temperature of 99.8F	2	21SEP2020	3/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1254 12541040	3^	MUSC	Myalgia/ generalized muscle soreness	1	30AUG2020	2/2	1	Yes		NA	R (31AUG2020)	N/N
16-55/ C459100 1 1254 12541051	3^	GENRL	Pyrexia/ fever of 100.5F	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1254 12541053	3^	GENRL	Fatigue/ fatigue	1	31AUG2020	1/3	2	Yes		NA	R (02SEP2020)	N/N
			Injection site pain/ Left arm injection site soreness	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541056	3^	GENRL	Fatigue/ fatigue	2	24SEP2020	2/4	2	Yes		NA	R (27SEP2020)	N/N
			Pain/ bodyache	2	24SEP2020	2/3	2	Yes		NA/TC	R (26SEP2020)	N/N
		METAB	Decreased appetite/ loss of appetite	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
		GASTR	Nausea/ nausea	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Dizziness/ lightheadedness	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
			Headache/ headache	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1254 12541057	3^	GENRL	Pyrexia/ fever of 102F	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
			Pyrexia/ fever of 104.9	2	22SEP2020	2/1	3	Yes		NA/TC	R (22SEP2020)	N/N
		RESP	Cough/ Cough	1	10SEP2020	11/1	1	No	O	NA	R (10SEP2020)	N/N
16-55/ C459100	3^	MUSC	Musculoskeletal chest pain/ Rib cage pain	1	06SEP2020	6/9	2	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1254 12541062		GENRL	Injection site pain/ Soreness at injection site	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1254 12541063	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	01SEP2020	1/3	1	Yes		NA/TC	R (03SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	22SEP2020	1/4	1	Yes		NA/TC	R (25SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Pain/ bodyache	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C459100 1 1254 12541066	3^	NERV	Somnolence/ drowsiness	1	09SEP2020	8/10	2	No	O	NA	R (18SEP2020)	N/N
		VASC	Hot flush/ worsening hot flashes	1	09SEP2020	8/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1254 12541067	3^	GENRL	Injection site pain/ injection site pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
		GASTR	Nausea/ nausea	1	03SEP2020	2/1	1	No	O	NA	R (03SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ muscle pain at injection site	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1254 12541068	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
1 1254 12541072		GENRL	Injection site pain/ soreness at injection site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1254 12541072	3^	MUSC	Pain in extremity/ RIGHT ARM SORENESS	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		METAB	Type 2 diabetes mellitus/ worsening of diabetes mellitus type 2	1	11SEP2020	10/C	2	No	O	NA/TC	N	N/N
		GENRL	Injection site pain/ soreness pf injection site	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ fever of 100.4F	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		MUSC	Back pain/ low back pain	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C459100 1 1254 12541077	3^	GENRL	Pain/ body aches generalized	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Chills/ chills	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
			Fatigue/ fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1254 12541080	3^	MUSC	Myalgia/ generalized muscle aches	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N	
		NERV	Headache/ headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N	
		GENRL	Injection site pain/ injection site pain	1	03SEP2020	1/3	1	Yes			NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	25SEP2020	2/7	1	Yes			NA	R (01OCT2020)	N/N
		GENRL	Pyrexia/ fever 100.4F	2	25SEP2020	2/1	2	Yes		NA/TC		R (25SEP2020)	N/N
		GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	28SEP2020	5/2	1	Yes			NA	R (29SEP2020)	N/N
16-55/ C459100 1 1254 12541081	3^	GENRL	Injection site pruritus/ ITCHY AT INJECTION SITE	2	28SEP2020	5/2	1	Yes		NA	R (29SEP2020)	N/N	
		GENRL	Injection site pain/ injection site pain	1	03SEP2020	1/3	2	Yes		NA	R (05SEP2020)	N/N	
16-55/ C459100 1 1254 12541083	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N	
		INV	Body temperature increased/ ELEVATED BODY TEMPERATURE 99.6F/36.6C	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541086	3^	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/4	1	Yes		NA	R (07SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C459100 1 1254 12541087	3^	GENRL	Injection site pain/ LEFT ARM SORENESS AT INJECTION SITE	1	03SEP2020	1/5	1	Yes		NA	R (07SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1254 12541090	3^	GASTR	Diarrhoea/ diarrhea	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1254 12541094	3^	EYE	Eye irritation/ mild burning sensation in both eyes	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ Injection site tenderness	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
			Pain/ Body ache	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
		NERV	Headache/ headache	1	04SEP2020	1/3	1	Yes		NA/TC	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)		
16-55/ C459100 11254 12541099		GENRL	Chills/ chills	2	27SEP2020	2/1	1	Yes		NA	R (27SEP2020)	N/N		
			Pain/ bodyache	2	27SEP2020	2/2	2	Yes		NA/TC	R (28SEP2020)	N/N		
			Pyrexia/ Fever at 100.4F	2	27SEP2020	2/1	2	Yes		NA/TC	R (27SEP2020)	N/N		
		NERV	Headache/ headache	2	27SEP2020	2/2	1	Yes		NA	R (28SEP2020)	N/N		
			GENRL	Injection site pain/ left arm injection site soreness	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N	
		3^	GENRL	Fatigue/ FATIGUE	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N	
				INV	Weight increased/ WEIGHT GAIN	1	10SEP2020	7/C	1	No	O	NA/TC	N	N/N
				GENRL	Injection site pain/ soreness at injection site	2	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
				GENRL	Chills/ chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
					Fatigue/ fatigue	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
				Pain/ bodyache	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N	
16-55/ C459100 11254 12541102				3^	PSYCH	Insomnia/ Insomnia	1	14SEP2020	10/2	2	No	O	NA	R (15SEP2020)

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541105	3^	GENRL	Chills/ CHILLS	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Pain/ bodyache	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C459100 1 1254 12541107	3^	GENRL	Injection site pain/ Soreness at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		PSYCH	Depression/ worsening of depression	2	OCT2020	3/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1254 12541111	3^	GENRL	Chills/ chills	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
			Pain/ generalized body ache	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1254 12541115	3^	GENRL	Injection site pain/ pain at injection site	2	30SEP2020	1/17	2	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1254 12541117	3^	RESP	Productive cough/ INCREASED PHELM	1	14SEP2020	5/45	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C459100 1 1254 12541119	3^	GASTR	Abdominal distension/ abdominal bloating	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541120	3^	GENRL	Diarrhoea/ diarrhea	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
			Fatigue/ fatigue	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
			Nausea/ nausea	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
			Headache/ headache	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ LEFT ARM INJECTION SITE SORENESS	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/Y
			Fatigue/ MILD FATIGUE	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
			Injection site pain/ Injection site pain	1	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
Fatigue/ fatigue			1	20SEP2020	2/1	2	Yes		NA	R (20SEP2020)	N/N	
MUSC	Myalgia/ muscle bodyaches	1	20SEP2020	2/1	2	Yes		NA/TC	R (20SEP2020)	N/N		
	NERV	Headache/ Headache	1	20SEP2020	2/1	2	Yes		NA/TC	R (20SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541126	3 [^]	MUSC	Pain in extremity/ pain right index finger	1	27SEP2020	9/2	1	No	O	NA	R (28SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	10OCT2020	1/3	2	Yes		NA/TC	R (12OCT2020)	N/N
		GENRL	Chills/ chills	2	11OCT2020	2/1	1	Yes		NA	R (11OCT2020)	N/N
			Pain/ body aches	2	11OCT2020	2/1	2	Yes		NA/TC	R (11OCT2020)	N/N
		INV	Heart rate increased/ elevated heart rate	2	11OCT2020	2/8	2	Yes		NA	R (18OCT2020)	N/N
		NERV	Headache/ headache	2	11OCT2020	2/2	2	Yes		NA/TC	R (12OCT2020)	N/N
		GENRL	Injection site pain/ injection site pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C459100 1 1254 12541134	3 [^]	GENRL	Injection site pain/ tenderness at injection site	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		NERV	Somnolence/ drowsiness	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		GENRL	Chills/ chills	1	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
		SKIN	Hyperhidrosis/ SWEATING	1	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
		GASTR	Nausea/ NAUSEA	1	14SEP2020	4/2	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541135	3^	SKIN	Hyperhidrosis/ sweating	2	02OCT2020	1/15	2	Yes		NA	R (16OCT2020)	N/N
		GASTR	Nausea/ nausea	2	03OCT2020	2/3	2	Yes		NA	R (05OCT2020)	N/N
		GENRL	Chills/ chills	2	04OCT2020	3/13	1	Yes		NA	R (16OCT2020)	N/N
		NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		GASTR	Nausea/ nausea	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		NERV	Lethargy/ Lethargy	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		GASTR	Abdominal pain upper/ stomach pain	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100 1 1254 12541140	3^	GENRL	Nausea/ nausea	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
			Injection site pain/ injection site pain	1	12SEP2020	1/15	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Injection site erythema/ erythema at injection site	1	13SEP2020	2/14	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ pain at injection site	2	03OCT2020	1/5	1	Yes		NA	R (07OCT2020)	N/N
		EYE	Eye irritation/ left eye irritation	1	12SEP2020	1/3	1	No	O	NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11254 12541142			Ocular hyperaemia/ left eye redness	1	12SEP2020	1/3	1	No	O	NA	R (14SEP2020)	N/N
		GENRL	Chills/ intermittent chills	1	12SEP2020	1/14	1	Yes		NA	R (25SEP2020)	N/N
		INJ&P	Maternal exposure during pregnancy/ Maternal Exposure During Pregnancy	1	12SEP2020	1/C		No	O	P	UNK	N/Y
		INV	Body temperature increased/ elevated body temperature at 100.0F	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Pyrexia/ fever at 102.0F	1	14SEP2020	3/1	2	Yes		NA/TC	R (14SEP2020)	N/N
		INV	Body temperature increased/ elevated body temperature at 100.0F	1	14SEP2020	3/2	2	Yes		NA/TC	R (15SEP2020)	N/N
		GASTR	Abdominal pain upper/ stomach pain	1	15SEP2020	4/1	2	No	O	NA/TC	R (15SEP2020)	N/N
		NERV	Headache/ headache intermittent	1	15SEP2020	4/11	2	Yes		NA/TC	R (25SEP2020)	N/N
		GASTR	Nausea/ Nausea	1	26SEP2020	15/C	1	No	O	NA	RG	N/N
		INV	Weight decreased/ weight loss	1	OCT2020	20/C	1	No	O	NA	N	N/N
		SKIN	Alopecia/ hair loss	1	OCT2020	20/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541144	3^	GASTR	Nausea/ worsening of Nausea	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	12SEP2020	1/6	1	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ Injection Site Tenderness	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	03OCT2020	1/5	1	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/ Soreness at injection site	2	03OCT2020	1/3	1	Yes		NA	R (05OCT2020)	N/N
		GENRL	Pyrexia/ fever 100.6F	2	04OCT2020	2/3	1	Yes		NA/TC	R (06OCT2020)	N/N
		GASTR	Diarrhoea/ diarrhea	2	06OCT2020	4/1	3	Yes		NA/TC	R (06OCT2020)	N/N
	Vomiting/ vomiting	2	06OCT2020	4/1	2	Yes		NA/TC	R (06OCT2020)	N/N		
16-55/ C459100 1 1254 12541145	3^	GENRL	Injection site pain/ Injection site pain	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
		INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	22SEP2020	11/C		No	O	NA	UNK	N/N
16-55/ C459100 1 1254 12541147	3^	GENRL	Injection site pain/ injection site pain	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541148	3^	GENRL	Fatigue/ fatigue	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
		REPRO	Premenstrual syndrome/ worsening of premenstrual syndrome symptoms	1	14SEP2020	3/4	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1254 12541151	3^	NERV	Headache/ headache	1	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C459100 1 1254 12541152	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
			Pain/ body ache	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Pain/ body aches	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1254 12541153	3^	GENRL	Fatigue/ FATIGUE	1	16SEP2020	3/25	2	Yes		NA	R (10OCT2020)	N/N
		PSYCH	Irritability/ IRRITABILITY	1	16SEP2020	3/42	2	No	O	NA	R (27OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1254 12541155	3^	GENRL	Injection site pain/ soreness at the injection site	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
1 1254 12541159		GENRL	Fatigue/ fatigue	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
			Pain/ bodyache	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		INV	Body temperature increased/ elevated body temperature of 99.9F	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1254 12541162	3^	SKIN	Pruritus/ generalized itching	1	20SEP2020	3/53	1	No	O	NA	R (11NOV2020)	N/N
16-55/ C459100 1 1254 12541163	3^	GENRL	Fatigue/ fatigue	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ injection site soreness	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ injection site pain	1	19SEP2020	1/4	1	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1254 12541165		GENRL	Injection site pain/ soreness at injection site	2	10OCT2020	1/4	1	Yes		NA	R (13OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	11OCT2020	2/2	1	Yes		NA	R (12OCT2020)	N/N
		NERV	Headache/ headache	2	11OCT2020	2/1	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C459100 1 1254 12541166	3^	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	1/3	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	10OCT2020	1/4	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1254 12541168	3^†	INFEC	Abscess limb/ abscess left thigh	2	28OCT2020	14/10	2	No	O	NA/TC	R (06NOV2020)	N/N
16-55/ C459100 1 1254 12541169	3^	MUSC	Back pain/ back pain	1	25SEP2020	2/5	2	Yes		NA/TC	R (29SEP2020)	N/N
		NERV	Headache/ headache	1	25SEP2020	2/5	2	Yes		NA/TC	R (29SEP2020)	N/N
		GENRL	Chills/ chills	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
			Fatigue/ fatigue	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541170	3^	GENRL	Injection site pain/ soreness at injection site	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
			Injection site swelling/ swelling at injection site	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
			RESP Rhinorrhoea/ runny nose	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
			Injection site pain/ left injection site pain	1	23SEP2020	1/4	1	Yes		NA	R (26SEP2020)	N/N
			GENRL Fatigue/ FATIGUE	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1254 12541173	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
			Injection site pain/ injection site soreness	1	23SEP2020	1/5	1	Yes		NA	R (27SEP2020)	N/N
			GENRL Chills/ chills	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
			Pyrexia/ fever at 100.6F	2	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
			MUSC Myalgia/ generalized muscle ache	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1254 12541176	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS LEFT ARM	1	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1254 12541177	3^	NERV	Headache/ HEADACHE	1	24SEP2020	2/4	1	Yes		NA/TC	R (27SEP2020)	N/N	
		GENRL	Injection site pain/ soreness at injection site	2	15OCT2020	1/4	2	Yes		NA/TC	R (18OCT2020)	N/N	
		GENRL	Fatigue/ fatigue	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N	
		NERV	Headache/ headache	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N	
	GENRL	Fatigue/ FATIGUE	1	23SEP2020	1/4	1	Yes		NA	R (26SEP2020)	N/N		
	GENRL	Chills/ CHILLS	1	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N		
	16-55/ C459100 1 1254 12541180	3^	GENRL	Injection site pain/ pain at injection site	1	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
			GENRL	Pain/ bodyache	1	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
GENRL			Fatigue/ fatigue	2	17OCT2020	2/3	2	Yes		NA	R (19OCT2020)	N/N	
MUSC			Myalgia/ generalized muscle pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
NERV	Headache/ headache	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N			
GASTR	Aphthous ulcer/ canker sore	2	18OCT2020	3/13	2	Yes		NA	R (30OCT2020)	N/N			

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541181	3^	GENRL	Injection site pain/ Injection site soreness	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1254 12541182	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1258 12581016	3^	GENRL	Fatigue/ fatigue	2	03OCT2020	10/6	1	No	O	NA	R (08OCT2020)	N/N
			Malaise/ Malaise	2	03OCT2020	10/6	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C459100 1 1258 12581044	3^	INFEC	Otitis media/ right otitis media	1	30SEP2020	7/7	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 1258 12581046	3^	INFEC	Otitis media/ right otitis media	1	08OCT2020	11/5	1	No	O	NA/TC	R (12OCT2020)	N/N
		RESP	Cough/ cough	1	08OCT2020	11/3	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1260 12601002	3^	NERV	Migraine without aura/ increased intensity of migraine without aura	1	27AUG2020	2/1	2	Yes		NA/TC	R (27AUG2020)	N/N
		GENRL	Fatigue/ fatigue	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1260 12601004	3^	GENRL	Injection site pain/ soreness at injection site	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
			Pain/ generalized body aches	2	16SEP2020	2/3	2	Yes		NA/TC	R (18SEP2020)	N/N
			Fatigue/ FATIGUE	2	05OCT2020	19/2	1	No	O	NA	R (06OCT2020)	N/N
			Malaise/ MALAISE	2	05OCT2020	19/2	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C459100 1 1260 12601005	3^	GENRL	Chills/ chills	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
			Fatigue/ fatigue	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1260 12601006	3^	GENRL	Pain/ generalized body aches	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ Soreness at injection site	1	27AUG2020	2/2	1	Yes		NA/TC	R (28AUG2020)	N/N
		MUSC	Arthralgia/ Left hand joint pain	1	27AUG2020	2/2	1	Yes		NA/TC	R (28AUG2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	16SEP2020	1/6	1	Yes		NA/TC	R (21SEP2020)	N/N
MUSC	Arthralgia/ joint pain left wrist/hand	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1260 12601007	3^	GASTR	Constipation/ constipation	2	15OCT2020	31/8	1	No	O	NA/TC/TCN	R (22OCT2020)	N/N
16-55/ C459100 1 1260 12601009	3^	GENRL	Injection site pain/ Soreness at Injection site	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ generalized myalgias	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 1 1260 12601012	3^	GENRL	Injection site pain/ soreness at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Fatigue/ fatigue	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
		NERV	Headache/ Headache	2	07OCT2020	20/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1260 12601013	3^	NERV	Headache/ intermittent episodes of headaches	1	29AUG2020	2/2	2	Yes		NA/TC	R (30AUG2020)	N/N
		GENRL	Fatigue/ fatigue	1	03SEP2020	7/2	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1260 12601014	3^	GENRL	Injection site pain/ Injection Site Soreness	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Malaise/ Malaise	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ Low Grade Fever (100.2 max)	2	18SEP2020	2/32	1	Yes		NA	R (19OCT2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	1	28AUG2020	1/4	1	Yes		NA/TC	R (31AUG2020)	N/N
		GENRL	Injection site pain/ Arm soreness at injection site	2	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
		16-55/ C459100 1 1260 12601016	3^		Pain/ body aches	1	29AUG2020	2/1	1	Yes		NA
	Pyrexia/ fever (99.3)			1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
GENRL	Chills/ Chills			2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1260 12601017	3^	GASTR	Fatigue/ Fatigue	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N	
			Injection site pain/ Arm soreness at injection site	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N	
			Pain/ Generalized body aches	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N	
			Diarrhoea/ diarrhea	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N	
			Injection site pain/ soreness at injection site	1	29AUG2020	2/5	1	Yes		NA	R (02SEP2020)	N/N	
			Injection site pain/ Injection site Soreness	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	
			Presyncope/ Vasovagal reaction to blood draw	2	16OCT2020	29/1	1	No	O	NA/TCN	R (16OCT2020)	N/N	
16-55/ C459100 1 1260 12601022	3^	GENRL	Injection site pain/ muscle pain at injection site	2	01OCT2020	16/3	1	No	O	NA	R (03OCT2020)	N/N	
16-55/ C459100 1 1260 12601024	3^	MUSC	Myalgia/ generalized muscle aches	1	31AUG2020	1/5	1	Yes		NA/TC	R (04SEP2020)	N/N	
			GENRL	Chills/ chills	1	01SEP2020	2/4	1	Yes		NA/TC	R (04SEP2020)	N/N
				Pyrexia/ fever 101.5 F	1	01SEP2020	2/4	2	Yes		NA/TC	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1260 12601029	3^	GENRL	Fatigue/ fatigue	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
			Injection site pain/ soreness at the site of injection	1	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1260 12601036	3^	GENRL	Injection site pain/ achy arm at site of injection	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
			Injection site pain/ soreness at injection site	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
			Pain/ generalized body aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1260 12601042	3^	GENRL	Injection site pain/ Soreness at injection site	1	01SEP2020	1/3	2	Yes		NA/TC	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	2/6	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C459100 1 1260 12601044	3^	GASTR	Diarrhoea/ diarrhea	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1260 12601045	3^	GENRL	Fatigue/ fatigue	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Chills/ chills	1	01SEP2020	1/3	1	Yes		NA/TC	R (03SEP2020)	N/N
			Injection site pain/ soreness at injection site	1	01SEP2020	1/3	1	Yes		NA/TC	R (03SEP2020)	N/N
16-55/ C459100 1 1260 12601047	3^	MUSC	Joint range of motion decreased/ unable to rotate right arm	1	01SEP2020	1/3	2	Yes		NA/TC	R (03SEP2020)	N/N
		GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/Y
		GENRL	Injection site pain/ soreness at injection site	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C459100 1 1260 12601050	3^	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/5	1	Yes		NA	R (28SEP2020)	N/N
			Injection site pain/ Soreness at injection site	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
			Pyrexia/ Fever (T-max 100.1)	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17SEP2020	16/8	1	Yes		NA	R (24SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1260 12601058	3^	GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N
		GASTR	Diarrhoea/ intermittent episodes of diarrhea	1	06SEP2020	3/4	2	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 1 1260 12601061	3^	GENRL	Fatigue/ Fatigue	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1260 12601063	3^	SKIN	Dermatitis contact/ Contact dermatitis	2	16OCT2020	22/3	1	No	O	NA/TC	R (18OCT2020)	N/N
		GENRL	Injection site pain/ soreness at the injection site	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
		NERV	Headache/ headache	1	08SEP2020	5/4	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C459100 1 1260 12601065	3^	GENRL	Injection site pain/ soreness at injection site	2	25SEP2020	1/4	2	Yes		NA/TC	R (28SEP2020)	N/N
16-55/ C459100 1 1260 12601067	3^	GENRL	Injection site pain/ soreness at injection site	1	05SEP2020	2/4	1	Yes		NA	R (08SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11260 12601068	3 [^]	GENRL	Injection site pain/ soreness at injection site	1	04SEP2020	1/7	2	Yes		NA	R (10SEP2020)	N/N
		GENRL	Chills/ chills	1	05SEP2020	2/6	2	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ fever	1	05SEP2020	2/6	2	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 11260 12601074	3 [^]	GENRL	Injection site pain/ Injection site pain - Left arm	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/Y
		MUSC	Myalgia/ Generalized Myalgia	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		NERV	Headache/ Headache	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
		GENRL	Pain/ Body Aches (Generalized)	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Pyrexia/ Fever (101.2 Max)	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
		NERV	Migraine with aura/ Migraine with aura	2	03OCT2020	4/3	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C459100	3 [^]	GENRL	Injection site pain/ soreness at injection site	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11260 12601075		MUSC	Tendon disorder/ worsening of tendopathy (hands)	2	18OCT2020	17/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C459100 11260 12601076	3^	GENRL	Fatigue/ Fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
			Injection site pain/ Soreness at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C459100 11260 12601077	3^	GENRL	Injection site pain/ soreness at injection site	1	08SEP2020	1/4	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 11260 12601084	3^	GENRL	Chills/ chills	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ fever	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		MUSC	Myalgia/ generalized myalgia	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Pain/ Body Aches	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 11260 12601085	3^	GENRL	Fatigue/ Fatigue	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)		
16-55/ C459100 1 1260 12601091	3^	MUSC	Injection site pain/ Injection site pain - Left arm	1	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/Y		
			Myalgia/ generalized Myalgia	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N		
		GENRL	Injection site pain/ pain at injection site	2	29SEP2020	1/4	1	Yes		NA	R (02OCT2020)	N/N		
			Pain/ generalized body aches	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N		
		GENRL	Fatigue/ fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N		
			Pyrexia/ fever	2	30SEP2020	2/2	2	Yes		NA/TC	R (01OCT2020)	N/N		
		16-55/ C459100 1 1260 12601092	3^	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
					Injection site pain/ soreness at injection site	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
				NERV	Headache/ Intermittent headaches	1	10SEP2020	2/4	2	Yes		NA/TC	R (13SEP2020)	N/N
				GENRL	Injection site pain/ soreness at injection site	2	03OCT2020	2/4	1	Yes		NA	R (06OCT2020)	N/N
NERV	Headache/ mild headaches	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N				
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1260 12601094	3^	GENRL	Injection site pain/ pain at injection site	2	01OCT2020	2/38	2	Yes		NA/TC	R (07NOV2020)	N/N
1 1260 12601098	3^	GASTR	Nausea/ Nausea	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
1 1260 12601099		GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
			Feeling hot/ feeling of warmth	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
			Injection site pain/ Soreness at injection site	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ Soreness at injection site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1260 12601100	3^	GENRL	Injection site pain/ Soreness at injection site	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1260 12601104	3^	GENRL	Injection site pain/ soreness at injection site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Chills/ chills	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		NERV	Somnolence/ Drowsiness	1	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N
		NERV	Headache/ headache	1	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at injection site	2	01OCT2020	1/3	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1260 12601108	3^	GENRL	Injection site pain/ soreness at injection site	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C459100	3^	GASTR	Diarrhoea/ diarrhea	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1260 12601110	3^	NERV	Headache/ headache	1	01OCT2020	22/1	1	No	O	NA	R (01OCT2020)	N/N
1 1260 12601111		NERV	Headache/ headache	2	02OCT2020	2/1	1	No	O	NA/TC	R (02OCT2020)	N/N
		NERV	Presyncope/ vasovagal pre syncopal lightheadness	2	02NOV2020	33/1	1	No	O	NA/TCN	R (02NOV2020)	N/N
16-55/ C459100 1 1260 12601112	3^	GENRL	Injection site pain/ Injection Site Pain - Left arm	1	15SEP2020	6/1	1	Yes		NA	R (15SEP2020)	N/N
		MUSC	Myalgia/ generalized Myalgia	1	17SEP2020	8/3	2	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Pain/ Generalized body aches	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1260 12601114	3^	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1260 12601115	3 [^]	NERV	Headache/ headache	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Chills/ chills	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
			Fatigue/ fatigue	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
			Injection site pain/ soreness at injection site	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
			Pain/ generalized body aches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		NERV	Dizziness/ dizziness	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	12SEP2020	3/2	1	Yes		NA	R (13SEP2020)	N/N
		NERV	Headache/ headache	1	12SEP2020	3/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Aches	2	01OCT2020	1/5	1	Yes		NA/TC	R (05OCT2020)	N/N
		NERV	Headache/ Headache (No aura)	2	01OCT2020	1/5	2	Yes		NA/TC	R (05OCT2020)	N/N
		GENRL	Injection site pain/ Soreness at injection site	2	02OCT2020	2/4	2	Yes		NA/TC	R (05OCT2020)	N/N
GENRL	Fatigue/ Fatigue	2	03OCT2020	3/3	1	Yes		NA	R (05OCT2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1260 12601118	3^	GENRL	Injection site pain/ soreness at injection site	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		NERV	Dizziness/ Dizziness	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1260 12601119	3^	GENRL	Injection site pain/ soreness at injection site	1	11SEP2020	1/5	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
			Injection site erythema/ redness at injection site	1	12SEP2020	2/4	1	Yes		NA	R (15SEP2020)	N/N
		METAB	Decreased appetite/ lack of appetite	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	04OCT2020	3/1	1	Yes		NA	R (04OCT2020)	N/N
			Injection site pain/ soreness at injection site	2	04OCT2020	3/3	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C459100 1 1260 12601120	3^	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
			Injection site pain/ Soreness at injection site	1	12SEP2020	2/4	1	Yes		NA	R (15SEP2020)	N/N
		MUSC	Myalgia/ Generalized muscle aches	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1260 12601123	3^	NERV	Headache/ Headache	1	12SEP2020	2/2	2	Yes		NA/TC	R (13SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	18SEP2020	8/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	01OCT2020	2/6	2	Yes		NA/TC	R (06OCT2020)	N/N
			Pain/ generalized body aches	2	01OCT2020	2/1	2	Yes		NA/TC	R (01OCT2020)	N/N
		NERV	Headache/ headache (no aura)	1	02OCT2020	18/2	1	No	O	NA	R (03OCT2020)	N/N
		GENRL	Chills/ Chills	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
			Fatigue/ Fatigue	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
			Pain/ Aches all over	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
		MUSC	Pain in extremity/ Left Arm Pain	1	17SEP2020	1/10	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ Headache	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C459100 1 1260 12601127	3^	GENRL	Feeling hot/ feeling of warmth all over body	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)		
16-55/ C459100 1 1260 12601128	3^	NERV	Injection site pain/ soreness at injection site	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N		
			Lethargy/ lethargy	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N		
		GENRL	Injection site pain/ pain at injection site	2	06OCT2020	1/5	1	Yes		NA	R (10OCT2020)	N/N		
			Fatigue/ fatigue	2	07OCT2020	2/6	1	Yes		NA	R (12OCT2020)	N/N		
		NERV	Pyrexia/ fever	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N		
			Headache/ headache	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N		
			Taste disorder/ change in taste	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N		
		GENRL	Pain/ achiness - generalized	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N		
		16-55/ C459100 1 1260 12601129	3^	GENRL	Injection site pain/ soreness at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		16-55/ C459100 1 1260 12601130	3^	CARD	Palpitations/ Intermittent Palpitations	1	24SEP2020	7/9	1	No	O	NA	R (02OCT2020)	N/N
SKIN	Rash/ small rash on bilateral wrists and bilateral top of the feet	2		23OCT2020	15/C	1	Yes		NA/TC	N	N/N			

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1260 12601132	3^	GENRL	Injection site pain/ Arm soreness at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		GASTR	Nausea/ Nausea	1	20SEP2020	3/1	1	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ Headache	1	20SEP2020	3/1	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Injection site swelling/ swelling at injection site	2	28OCT2020	20/7	1	No	O	NA	R (03NOV2020)	N/N
16-55/ C459100 1 1261 12611001	3^	GENRL	Injection site pain/ Injection site pain	2	16SEP2020	1/8	1	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	17SEP2020	2/7	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1261 12611005	3^	SKIN	Urticaria/ Urticarial abdominal rash	1	29AUG2020	3/1	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 1 1261 12611006	3^	GENRL	Chills/ CHILLS - ADVERSE REACTION TO VACCINATION 1	1	28AUG2020	2/3	1	Yes		NA/TC	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1261 12611009	3^	MUSC	Myalgia/ DIFFUSE MYALGIA - ADVERSE REACTION TO VACCINATION 1	1	28AUG2020	2/3	1	Yes		NA/TC	R (30AUG2020)	N/N
		NERV	Headache/ HEADACHE - ADVERSE REACTION TO VACCINATION 1	1	28AUG2020	2/3	1	Yes		NA/TC	R (30AUG2020)	N/N
		INFEC	Abscess/ Lip Abscess	2	23SEP2020	7/9	3	No	O	NA/TC/TCN	R (01OCT2020)	Y/N
			Cellulitis/ Lip cellulitis	2	23SEP2020	7/9	3	No	O	NA/TC	R (01OCT2020)	Y/N
		IMMUN	Drug hypersensitivity/ Hypersensitivity to antibiotics	2	26SEP2020	10/2	3	No	CD	NA/TC	R (27SEP2020)	Y/N
		GENRL	Injection site bruising/ Local bruising at injection site	1	29AUG2020	2/5	2	Yes		NA/TC/TCN	R (02SEP2020)	N/N
		GENRL	Injection site pain/ Local myalgia/tenderness at injection site	1	29AUG2020	2/5	2	Yes		NA/TC/TCN	R (02SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
MUSC	Arthralgia/ Arthralgia- generalized (not injection site arthralgia)	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11261 12611013	3^	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
			Malaise/ Malaise	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		MUSC	Myalgia/ Diffuse Myalgia	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C459100 11261 12611017	3^	GENRL	Injection site pain/ Localized myalgia at injection site	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
				Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)
16-55/ C459100 11261 12611020	3^	MUSC	Arthralgia/ Left shoulder pain	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		MUSC	Arthralgia/ Left shoulder pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100	3^	INFEC	Conjunctivitis/ Conjunctivitis	2	21SEP2020	1/8	2	No	O	NA	R (28SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1261 12611022	3^	GENRL	Adverse drug reaction/ Systemic injection reaction	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
1 1261 12611025			Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Fatigue/ Fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ Diffuse Myalgia	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1261 12611029	3^	GENRL	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ Headache	2	25SEP2020	2/2	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C459100 1 1261 12611030	3^	NERV	Syncope/ Vasovagal syncope	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	28SEP2020	6/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C459100 1 1261 12611038	3^	GENRL	Adverse drug reaction/ Systemic injection reaction	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1261 12611042	3^	GENRL	Chills/ Chills	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Myalgia/ Diffuse Myalgia	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Chills/ Chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		IMMUN	Immunisation reaction/ Vaccine Reaction	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		MUSC	Myalgia/ Diffuse Myalgia	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 1261 12611047	3^	NERV	Headache/ Headache	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
			GENRL	Malaise/ Malaise	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)
		MUSC	Pyrexia/ Fever	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
			Myalgia/ Diffuse Myalgia	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
			GENRL	Chills/ Chills	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)
	Fatigue/ Fatigue	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11261 12611051	3^	IMMUN	Immunisation reaction/ Systemic vaccine reaction	2	26SEP2020	2/3	2	Yes		NA	R (28SEP2020)	N/N
		MUSC	Myalgia/ Diffuse Myalgia	2	26SEP2020	2/3	2	Yes		NA	R (28SEP2020)	N/N
		GENRL	Injection site bruising/ Injection site bruising	2	30SEP2020	2/10	1	Yes		NA	R (09OCT2020)	N/N
			Injection site erythema/ Injection site redness (7cm in diameter using caliper)	2	30SEP2020	2/10	2	Yes		NA	R (09OCT2020)	N/N
			Injection site swelling/ Injection site swelling (7 cm diameter using caliper)	2	30SEP2020	2/10	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 11261 12611054	3^	GENRL	Pyrexia/ Fever	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		INJ&P	Muscle strain/ Left lower back strain secondary to exercise	1	13SEP2020	6/19	2	No	O	NA/TC	R (01OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
			Injection site pain/ Pain at injection site	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
			Pyrexia/ Fever	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1261 12611058	3^	GENRL	Injection site erythema/ Erythema at Injection site	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
1 1261 12611059			Injection site pain/ Injection site pain	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
			Injection site warmth/ Warmth over injection site	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	2/5	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C459100 1 1261 12611060	3^	GASTR	Diarrhoea/ Diarrhea	1	14SEP2020	6/1	1	No	O	NA	R (14SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
			Injection site pain/ Injection site pain	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 1261 12611063	3^	GENRL	Adverse drug reaction/ Systemic injection reaction	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Chills/ Chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		MUSC	Myalgia/ DIFFUSE MYALGIA -	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1261 12611065	3^	NERV	ADVERSE REACTION TO VACCINATION 2 Headache/ HEADACHE - ADVERSE REACTION TO VACCINATION 2	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Injection site pain/ Injection site arm soreness	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100 1 1261 12611070	3^	MUSC	Myalgia/ Diffuse myalgia	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		GASTR	Aphthous ulcer/ Worsening frequency of canker sores	1	16SEP2020	7/25	1	No	O	NA	R (10OCT2020)	N/N
16-55/ C459100 1 1261 12611071	3^	SKIN	Dermatitis/ Facial dermatitis	2	25OCT2020	25/7	1	No	O	NA	R (31OCT2020)	N/N
		GENRL	Malaise/ Malaise	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C459100	3^	MUSC	Myalgia/ Diffuse myalgias	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Chills/ CHILLS - ADVERSE	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11261 12611074			REACTION TO VACCINATION 1									
			Pyrexia/ FEVER SECONDARY TO VACCINATION 1	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		IMMUN	Immunisation reaction/ Systemic Vaccine Reaction	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Myalgia/ DIFFUSE MYALGIA - ADVERSE REACTION TO VACCINATION 1	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		NERV	Headache/ HEADACHE - ADVERSE REACTION TO VACCINATION 1	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		INJ&P	Corneal abrasion/ Corneal Abrasion	1	18SEP2020	8/27	2	No	O	NA/TC	R (14OCT2020)	N/N
		GENRL	Chills/ CHILLS - ADVERSE REACTION TO VACCINATION 2	2	02OCT2020	1/2	3	Yes		NA/TC	R (03OCT2020)	N/N
			Pyrexia/ FEVER SECONDARY TO VACCINATION 2	2	02OCT2020	1/2	3	Yes		NA/TC	R (03OCT2020)	N/N
		MUSC	Arthralgia/ DIFFUSE GENERALIZED ARTHRALGIA AS REACTION RELATED TO 2ND VACCINATION	2	02OCT2020	1/2	3	Yes		NA/TC	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11261 12611077	3^	SKIN	Myalgia/ MYALGIA - ADVERSE REACTION TO VACCINATION 2	2	02OCT2020	1/2	3	Yes		NA/TC	R (03OCT2020)	N/N
			Urticaria/ Hives around neck	1	30SEP2020	20/2	1	No	O	NA/TC	R (01OCT2020)	N/N
			Immunisation reaction/ Systemic vaccine reaction	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
			Arthralgia/ Arthralgias secondary to vaccine reaction - diffuse generalized	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
			Myalgia/ Diffuse Myalgia secondary to vaccine reaction	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C459100 11264 12641013	3^	GASTR	Headache/ Headache secondary to vaccine	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
			Dyspepsia/ Heartburn	2	30SEP2020	19/1	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C459100 11264 12641014	3^	MUSC	Myalgia/ myalgia	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
		GASTR	Diarrhoea/ diarrhea	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1264 12641017	3^	SKIN	Pain of skin/ Scalp pain	1	07SEP2020	17/10	2	No	O	NA/TC/TCN	R (16SEP2020)	N/N
16-55/ C459100 1 1264 12641021	3^	CARD	Sinus tachycardia/ Sinus tachycardia	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Chills/ Chills	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
			Fatigue/ Fatigue	2	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
			Injection site pain/ Injection site pain	2	13SEP2020	2/2	2	Yes		NA/TC	R (14SEP2020)	N/N
			Pyrexia/ Fever	2	13SEP2020	2/2	2	Yes		NA/TC	R (14SEP2020)	N/N
		NERV	Disturbance in attention/ Concentration impairment	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	14SEP2020	3/2	1	Yes		NA	R (15SEP2020)	N/N
		RESP	Rhinorrhoea/ Rhinorrhea	2	15SEP2020	4/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1264 12641025	3^	GENRL	Chills/ Chills	2	12SEP2020	1/2	2	Yes		NA/TC	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1264 12641028	3^	REPRO	Fatigue/ Fatigue	2	12SEP2020	1/2	2	No	O	NA/TC	RS (13SEP2020)	N/N
			Menorrhagia/ Heavy menstruation	2	10OCT2020	29/7	2	Yes		NA	RS (16OCT2020)	N/N
		Menstruation irregular/ Irregular menstruation	2	10OCT2020	29/7	2	Yes		NA	RS (16OCT2020)	N/N	
		GENRL	Chills/ Chills	2	13SEP2020	1/2	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C459100 1 1264 12641032	3^	MUSC	Arthralgia/ Arthralgia	2	13SEP2020	1/2	1	Yes		NA	R (14SEP2020)	N/N
		METAB	Decreased appetite/ loss of appetite	1	24AUG2020	2/3	1	Yes		NA	R (26AUG2020)	N/N
		NERV	Presyncope/ presyncope	1	27AUG2020	5/1	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C459100 1 1264 12641037	3^	INFEC	Tinea infection/ ring worm	1	31AUG2020	8/34	1	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C459100 1 1264 12641049	3^	EAR	Vertigo/ Vertigo	1	07SEP2020	14/3	1	Yes		NA	R (09SEP2020)	N/N
		EAR	Vertigo/ Vertigo	2	15SEP2020	2/11	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11264 12641065	3^	GENRL	Chills/ Chills	2	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
			Fatigue/ Fatigue	2	17SEP2020	1/3	2	Yes		NA/TC	R (19SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	17SEP2020	1/3	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C459100 11264 12641070	3^	GENRL	Fatigue/ Fatigue	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C459100 11264 12641072	3^	MUSC	Myalgia/ Myalgia (persistent soreness in left deltoid)	2	19SEP2020	2/C	1	No	O	NA	N	N/N
16-55/ C459100 11264 12641073	3^	GENRL	Swelling face/ Swelling in lower jaw	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C459100 11264 12641082	3^	CARD	Tachycardia/ Tachycardia	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Arthralgia/ Arthralgia	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1264 12641083	3^	NERV	Myalgia/ Myalgia	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N
			Headache/ Headache	2	21SEP2020	1/4	2	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Back pain/ Back pain	1	02SEP2020	3/7	2	No	O	NA/TC	R (08SEP2020)	N/N
16-55/ C459100 1 1264 12641088	3^	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1264 12641090	3^		Injection site pain/ Pain at injection site	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ Fever	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1264 12641093	3^	INFEC	Wound infection/ Wound infection	2	14OCT2020	24/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11264 12641113			Injection site pain/ Pain at injection site	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 11264 12641116	3^	GENRL	Chills/ Chills	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
			Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 11264 12641123	3^	GENRL	Injection site pain/ Pain at injection site	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	28SEP2020	1/1	2	Yes		NA/TC	R (28SEP2020)	N/N
16-55/ C459100 11264 12641141	3^	GASTR	Diarrhoea/ Diarrhea	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		GASTR	Vomiting/ Vomiting	2	13OCT2020	15/6	1	No	O	NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1264 12641145	3^	GASTR	Umbilical hernia/ Umbilical hernia	1	13SEP2020	4/C	2	No	O	NA/TC/TCN	RG	N/N
		METAB	Decreased appetite/ Loss of appetite	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	30SEP2020	2/3	2	Yes		NA	R (02OCT2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1264 12641157	3^	GENRL	Influenza like illness/ Flu-like symptoms	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1264 12641158	3^	GENRL	Influenza like illness/ Flu-like symptoms	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C459100 1 1264 12641162	3^	GENRL	Injection site pain/ Pain at injection site	2	06OCT2020	1/8	2	Yes		NA	R (13OCT2020)	N/N
		VASC	Flushing/ Facial flushing	2	02NOV2020	28/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1264 12641168	3^	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1264 12641171	3^	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
			Influenza like illness/ Flu-like symptoms	2	06OCT2020	1/3	1	Yes		NA/TC	R (08OCT2020)	N/N
		METAB	Decreased appetite/ Anorexia	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		NERV	Headache/ Headache	2	06OCT2020	1/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1264 12641173	3^	GASTR	Nausea/ Nausea	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Malaise/ Malaise	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ Headache	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C459100 1 1264 12641177	3^	MUSC	Pain in extremity/ Arm Soreness	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
		RESP	Oropharyngeal pain/ Sore throat	2	10OCT2020	2/2	1	No	O	NA	R (11OCT2020)	N/N
16-55/ C459100 1 1264 12641181	3^	BLOOD	Lymph node pain/ Lymph node pain	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11264 12641185	3^	GENRL	Chills/ Chills	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 11264 12641186	3^	GENRL	Chills/ Chills	1	01OCT2020	11/32	2	No	O	NA/TC	R (01NOV2020)	N/N
			Fatigue/ Fatigue	1	01OCT2020	11/32	1	No	O	NA	R (01NOV2020)	N/N
		MUSC	Myalgia/ Myalgia	1	01OCT2020	11/37	2	No	O	NA	R (06NOV2020)	N/N
16-55/ C459100 11264 12641187	3^	GENRL	Influenza like illness/ Flu-like symptoms	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
			Injection site pain/ Injection site pain	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N
		NERV	Headache/ Headache	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 11264 12641190	3^	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
		NERV	Headache/ Headache	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1264 12641197			Fatigue/ Fatigue	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
		GASTR	Abdominal pain upper/ Stomach pain	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		MUSC	Arthralgia/ Arthralgia	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1264 12641200	3^	GENRL	Chills/ Chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
			Pyrexia/ Fever	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1264 12641206	3^	GASTR	Nausea/ Nausea	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		MUSC	Arthralgia/ Arthralgia	2	12OCT2020	1/C	2	Yes		NA/TC	RG	N/N
		NERV	Hyperaesthesia/ Increased skin sensitivity	2	12OCT2020	1/C	1	Yes		NA	RG	N/N
		GENRL	Injection site pain/ Injection site pain	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1264 12641208	3^	GENRL	Fatigue/ Fatigue	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1265 12651004	3^	GENRL	Injection site pain/ Pain at injection site (left deltoid)	2	31OCT2020	48/4	1	No	O	NA	R (03NOV2020)	N/N
16-55/ C459100 1 1265 12651010	3^	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/1	2	No	O	NA	R (28AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	29AUG2020	3/1	2	No	O	NA	R (29AUG2020)	N/N
16-55/ C459100 1 1265 12651013	3^	GENRL	Fatigue/ Mild fatigue	2	02OCT2020	2/2	1	No	O	NA	R (03OCT2020)	N/N
			Injection site pain/ Soreness at injection site	2	02OCT2020	2/2	1	No	O	NA	R (03OCT2020)	N/N
		MUSC	Myalgia/ New or increased muscle pain	2	02OCT2020	2/2	1	No	O	NA	R (03OCT2020)	N/N
16-55/ C459100 1 1265 12651016	3^	MUSC	Myalgia/ New or increased muscle pain	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C459100 1 1265 12651025	3^	INJ&P	Vaccination complication/ Vaccination adverse reaction	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1265 12651029	3^	INJ&P	Vaccination complication/ Vaccination Adverse Reaction	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C459100 1 1265 12651037	3^	GASTR	Abdominal mass/ Abdominal lump	1	2020	1/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1265 12651040	3^	INFEC	Herpes simplex/ Herpes simplex outbreak	2	10OCT2020	17/11	1	No	O	NA	R (20OCT2020)	N/N
16-55/ C459100 1 1265 12651043	3^	RESP	Rhinitis allergic/ Allergic rhinitis	2	28OCT2020	36/2	1	No	O	NA	R (29OCT2020)	N/N
16-55/ C459100 1 1265 12651044	3^	GENRL	Pain/ Diffuse body ache	1	21SEP2020	20/3	3	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ Fever	1	21SEP2020	20/3	3	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 1265 12651059	3^	EAR	Vertigo positional/ Benign positional vertigo	1	12SEP2020	9/1	1	No	O	NA/TCN	R (12SEP2020)	N/N
16-55/ C459100 1 1265 12651062	3^	GENRL	Fatigue/ Fatigue	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Arthralgia/ Arthralgias	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
			Myalgia/ Myalgias	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C459100 1 1265 12651065	3^	MUSC	Pain in extremity/ Sore arm	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C459100 1 1265 12651079	3^	GENRL	Pyrexia/ Fever	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
		NERV	Headache/ Headache	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C459100 1 1265 12651081	3^	RESP	Upper-airway cough syndrome/ Post nasal drip	2	30SEP2020	2/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1265 12651090	3^	GASTR	Constipation/ Constipation with left lower quadrant pain	1	14SEP2020	5/1	2	No	O	NA/TC	R (14SEP2020)	N/N
16-55/ C459100 1 1265 12651097	3^	MUSC	Tenosynovitis stenosaurs/ De Quervain's tenosynovitis	2	09OCT2020	9/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1265 12651099	3^	GASTR	Dyspepsia/ Dyspepsia	1	25SEP2020	15/C	1	No	CD	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1265 12651101	3 [^]	METAB	Hypoglycaemia/ Hypoglycemia	1	12SEP2020	2/2	3	No	CD	NA/TC	R (13SEP2020)	Y/N
		GASTR	Abdominal pain/ Abdominal pain	1	25SEP2020	15/14	2	No	O	NA/TC	R (08OCT2020)	N/N
		PSYCH	Confusional state/ Confusion/altered mental status	1	28SEP2020	18/2	2	No	CD	NA	R (29SEP2020)	N/N
		IMMUN	Hypersensitivity/ Allergic reaction	2	30OCT2020	31/3	1	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C459100 1 1265 12651136	3 [^]	MUSC	Back pain/ Lower back pain	2	26OCT2020	19/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1265 12651138	3 [^]	GENRL	Fatigue/ Mild fatigue	2	13OCT2020	6/4	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1265 12651143	3 ^{^†}	GASTR	Diarrhoea/ Diarrhea	2	20OCT2020	14/3	1	No	O	NA	R (22OCT2020)	N/N
		EYE	Meibomianitis/ Right eye meibomitis	2	24OCT2020	18/C	1	No	O	NA/TC	N	N/N
		INFECTION	Conjunctivitis/ Right eye conjunctivitis	2	24OCT2020	18/C	1	No	O	NA/TC	N	N/N
16-55/ C459100	3 [^]	GASTR	Toothache/ TOOTH PAIN	1	06OCT2020	19/3	1	No	O	NA/TC	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1265 12651145		GENRL	Pyrexia/ FEVER	1	06OCT2020	19/3	1	No	O	NA/TC	R (08OCT2020)	N/N
16-55/ C459100 1 1265 12651149	3^	UNC	BOTH UNDERARM LYMPH NODE@@/ Both underarm lymph node	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1265 12651151	3^	GASTR	Rectal haemorrhage/ Rectal bleeding	2	28OCT2020	15/6	1	No	O	NA	R (02NOV2020)	N/N
16-55/ C459100 1 1265 12651153	3^	RESP	Asthma/ Asthma exacerbation	1	28SEP2020	8/1	1	No	O	NA/TC	R (28SEP2020)	N/N
		EYE	Amaurosis fugax/ Right eye blindness, diagnosed with Right Amaurosis Fugax	2	01NOV2020	20/1	2	No	O	NA	R (01NOV2020)	N/N
16-55/ C459100 1 1265 12651155	3^	GENRL	Fatigue/ Slight fatigue	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Injection site discomfort/ Discomfort at injection site	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1265 12651161	3^	INFEC	Gastroenteritis/ Gastroenteritis	1	11OCT2020	20/2	1	No	O	NA	R (12OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1265 12651168	3 [^]	MUSC	Back pain/ Lower back pain	1	25SEP2020	3/3	1	No	O	NA	R (27SEP2020)	N/N
		RENAL	Pollakiuria/ Frequent Urination	1	25SEP2020	3/3	1	No	O	NA	R (27SEP2020)	N/N
		RENAL	Costovertebral angle tenderness/ Costovertebral angle tenderness	1	28SEP2020	6/4	1	No	O	NA	R (01OCT2020)	N/N
			Pollakiuria/ Urinary frequency	1	28SEP2020	6/4	1	No	O	NA	R (01OCT2020)	N/N
		MUSC	Back pain/ Lower back pain	2	17OCT2020	4/3	1	No	O	NA	R (19OCT2020)	N/N
		RENAL	Pollakiuria/ Frequent urination	2	17OCT2020	4/3	1	No	O	NA	R (19OCT2020)	N/N
16-55/ C459100 1 1265 12651173	3 [^]	RESP	Rhinorrhoea/ RUNNY NOSE	2	17OCT2020	5/4	1	No	O	NA	R (20OCT2020)	N/N
16-55/ C459100 1 1265 12651174	3 [^]	GENRL	Sensation of foreign body/ Globus Sensation	1	14OCT2020	21/7	1	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C459100 1 1265 12651180	3 [^]	REPRO	Ovarian cyst/ New diagnosis of left ovarian complex cyst	1	08OCT2020	14/C	1	No	O	NA	N	N/N
16-55/ C459100	3 ^{^†}	NERV	Hypoesthesia/ Left arm numbness	2	17OCT2020	2/13	1	No	O	NA	R (29OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1265 12651186												
16-55/ C459100	3^	GENRL	Chills/ chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
1 1269 12691016			Pyrexia/ fever	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		RESP	Oropharyngeal pain/ sore throat	2	23SEP2020	14/5	1	No	O	NA	R (27SEP2020)	N/N
16-55/ C459100	3^	NERV	Headache/ headache	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
1 1269 12691022			Myalgia/ muscle aches	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	13SEP2020	3/3	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Chills/ chills	2	13SEP2020	3/1	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C459100	3^	NERV	Headache/ headache	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
1 1269 12691029			Somnolence/ drowsiness	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C459100	3^	GENRL	Chills/ chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1269 12691042			Fatigue/ fatigue	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
		MUSC	Pain in extremity/ arm soreness	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C459100 1 1269 12691050	3^	RESP	Dyspnoea/ Shortness of breath	1	28AUG2020	4/1	1	No	O	NA/TC	R (28AUG2020)	N/N
			Nasal congestion/ Nasal congestion	1	28AUG2020	4/1	1	No	O	NA/TC	R (28AUG2020)	N/N
		RESP	Dyspnoea/ Shortness of breath	2	15SEP2020	1/1	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C459100 1 1269 12691056	3^	GENRL	Chills/ chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
			Pyrexia/ fever	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
		NERV	Headache/ headache	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C459100 1 1269 12691058	3^	GENRL	Chills/ chills	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
			Pyrexia/ fever	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1269 12691063	3^	MUSC	Myalgia/ body muscle aches	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Chills/ chills	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1269 12691064	3^	MUSC	Myalgia/ muscle aches	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ headache	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Injection site pain/ soreness at injection site	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Headache/ headache	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1269 12691065	3^	GENRL	Chills/ chills	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Chills/ chills	1	29AUG2020	3/1	1	Yes		NA	R (29AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 11269 12691076	3^	GENRL	Pyrexia/ Fever	1	29AUG2020	3/1	2	Yes		NA/TC	R (29AUG2020)	N/N	
			RESP	Nasal congestion/ nasal congestion	1	29AUG2020	3/1	1	Yes		NA	R (29AUG2020)	N/N
			GENRL	Fatigue/ fatigue	1	03SEP2020	8/1	1	No	O	NA	R (03SEP2020)	N/N
			RESP	Cough/ cough	1	03SEP2020	8/1	1	No	O	NA/TC	R (03SEP2020)	N/N
				Dyspnoea/ shortness of breath	1	03SEP2020	8/1	1	No	O	NA/TC	R (03SEP2020)	N/N
			GASTR	Diarrhoea/ diarrhea	1	07SEP2020	11/6	1	No	O	NA/TC	R (12SEP2020)	N/N
16-55/ C459100 11269 12691078	3^	GENRL	Nausea/ nausea	1	07SEP2020	11/6	1	No	O	NA/TC	R (12SEP2020)	N/N	
			Vomiting/ vomiting	1	07SEP2020	11/1	1	No	O	NA/TC	R (07SEP2020)	N/N	
			Chills/ chills	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N	
				Fatigue/ fatigue	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
	METAB	Decreased appetite/ loss of appetite	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N		
16-55/ C459100	3^	GENRL	Mucosal disorder/ increased mucus production	2	04OCT2020	14/3	1	No	O	NA	R (06OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1269 12691087		RESP	Throat irritation/ scratchy throat	2	04OCT2020	14/3	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C459100 1 1269 12691088	3^	GASTR	Abdominal pain lower/ lower abdominal pain	2	22SEP2020	2/7	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C459100 1 1269 12691091	3^	GENRL	Injection site pain/ soreness at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Chills/ chills	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1269 12691094	3^	GENRL	Chills/ chills	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Pyrexia/ fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C459100 1 1269 12691097	3^	CARD	Palpitations/ palpitation	1	09SEP2020	9/1	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Chills/ chills	1	09SEP2020	9/1	1	Yes		NA/TC	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 11269 12691105	3^	GENRL	Pyrexia/ fever	1	09SEP2020	9/1	1	Yes		NA/TC	R (09SEP2020)	N/N	
			MUSC	Myalgia/ muscle aches	1	09SEP2020	9/1	1	Yes		NA/TC	R (09SEP2020)	N/N
			INJ&P	Facial bones fracture/ fractured nose	1	17SEP2020	17/5	2	No	O	NA/TC	R (21SEP2020)	N/N
			NERV	Pyrexia/ fever	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
16-55/ C459100 11269 12691116	3^	GENRL	Ageusia/ loss of taste	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N	
			NERV	Headache/ headache	1	02SEP2020	1/3	1	Yes		NA/TC	R (04SEP2020)	N/N
			MUSC	Pyrexia/ fever	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C459100 11269 12691125	3^	GENRL	Myalgia/ muscle aches	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
			NERV	Chills/ chills	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
			NERV	Injection site pain/ soreness at injection site	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
			Pyrexia/ fever	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1269 12691126	3^	MUSC	Myalgia/ myalgias	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		GASTR	Paraesthesia oral/ tingling in mouth,lips and tongue	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Chest discomfort/ chest pressure	1	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		MUSC	Arthralgia/ achy joints	1	10SEP2020	2/3	1	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Hypogeusia/ diminished sense of taste	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Hyposmia/ Diminished sense of smell	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		RESP	Dyspnoea/ shortness of breath	1	10SEP2020	2/1	1	No	O	NA	R (10SEP2020)	N/N
			Oropharyngeal discomfort/ throat discomfort	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Chills/ chills	1	12SEP2020	4/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		RESP	Cough/ dry cough	1	16SEP2020	8/2	1	No	O	NA	R (17SEP2020)	N/N
16-55/ C459100	3^		Dyspnoea/ shortness of breath	1	16SEP2020	8/2	1	No	O	NA	R (17SEP2020)	N/N
			Oropharyngeal pain/ sore throat	1	16SEP2020	8/2	1	No	O	NA/TC	R (17SEP2020)	N/N
		GENRL	Injection site pain/ tenderness at injection site	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1269 12691127		GENRL	Fatigue/ fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Pyrexia/ fever	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1269 12691129	3^	GENRL	Fatigue/ fatigue	2	03OCT2020	4/2	1	No	O	NA	R (04OCT2020)	N/N
			Injection site pain/ muscle pain at the injection site	2	03OCT2020	4/2	1	Yes		NA	R (04OCT2020)	N/N
		PSYCH	Insomnia/ insomnia	2	03OCT2020	4/2	1	No	O	NA	R (04OCT2020)	N/N
16-55/ C459100 1 1269 12691136	3^	GENRL	Chills/ chills	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
			Malaise/ malaise	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
			Pyrexia/ fever	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
		MUSC	Myalgia/ muscle soreness	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C459100	3^	GASTR	Nausea/ Nausea	1	25AUG2020	1/1	1	Yes		NA/TC	R (25AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1270 12701003												
16-55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	1/4	1	Yes		NA	R (29AUG2020)	N/N
1 1270 12701011												
		NERV	Headache/ Headache	1	26AUG2020	1/3	1	Yes		NA/TC	R (28AUG2020)	N/N
16-55/ C459100	3^	SKIN	Skin irritation/ Worsening skin irritation in arm pits	2	21OCT2020	35/C	1	No	O	NA/TC	N	N/N
1 1270 12701015												
16-55/ C459100	3^	GENRL	Pyrexia/ Fever	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
1 1270 12701018												
16-55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	30AUG2020	4/3	1	Yes		NA	R (01SEP2020)	N/N
1 1270 12701020												
		GENRL	Fatigue/ Fatigue	2	19SEP2020	3/3	2	Yes		NA	R (21SEP2020)	N/N
			Pain/ Body Aches	2	19SEP2020	3/3	2	Yes		NA	R (21SEP2020)	N/N
16-55/ C459100	3^	MUSC	Flank pain/ Flank Pain	2	01OCT2020	14/C	1	No	O	NA	N	N/N
1 1270 12701022												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1270 12701025	3^	MUSC	Muscle spasms/ Muscle Spasm of Back	2	01OCT2020	14/C	1	No	O	NA	N	N/N
			Spinal osteoarthritis/ Osteoarthritis of Spine	2	01OCT2020	14/C	1	No	O	NA/TC	N	N/N
			Arthralgia/ Left wrist joint pain	1	15SEP2020	19/8	1	No	O	NA/TC/TCN	R (22SEP2020)	N/N
16-55/ C459100 1 1270 12701030	3^	GENRL	Pyrexia/ Fever	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 1270 12701034	3^	NERV	Headache/ Headache	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Chills/ Chills	1	04SEP2020	5/2	1	Yes		NA	R (05SEP2020)	N/N
		RESP	Upper-airway cough syndrome/ Postnasal drip	1	04SEP2020	5/2	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C459100 1 1270 12701037	3^	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INV	Alanine aminotransferase increased/ Increased ALT	2	15OCT2020	24/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1270 12701051	3^	GENRL	Chills/ Chills	1	23SEP2020	22/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C459100 1 1270 12701056	3^	INFEC	Acute sinusitis/ Acute Sinusitis	1	19OCT2020	47/10	1	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C459100 1 1270 12701065	3^	REPRO	Postmenopausal haemorrhage/ Post menopausal bleeding	1	11SEP2020	8/12	1	No	O	NA	R (22SEP2020)	N/N
		INV	Blood thyroid stimulating hormone increased/ Elevated Thyroid Stimulating Hormone Lab Test	2	19OCT2020	25/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1270 12701068	3^	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C459100 1 1270 12701069	3^	INFEC	Appendicitis/ APPENDICITIS	1	20SEP2020	17/3	3	No	O	NA/TC/TCN	R (22SEP2020)	Y/N
		INV	Blood cholesterol increased/ Elevated Cholesterol	2	08OCT2020	9/C	1	No	O	NA/TCN	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Low density lipoprotein increased/ Elevated Low-Density Lipoprotein	2	08OCT2020	9/C	1	No	O	NA/TCN	N	N/N
16-55/ C459100 1 1270 12701071	3^	MUSC	Rotator cuff syndrome/ Impingement Syndrome of Bilateral Shoulders	1	18SEP2020	11/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1270 12701074	3^	SKIN	Rash/ Rash to Chest	1	12SEP2020	5/15	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 1270 12701076	3^	GASTR	Nausea/ Nausea*		08SEP2020	1/1	1	No	O	NA	R (08SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	30SEP2020	1/2	2	No	O	NA	R (01OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		METAB	Decreased appetite/ Decreased Appetite	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1270 12701082	3^	MUSC	Arthralgia/ New joint pains	1	10SEP2020	2/4	2	Yes		NA	R (13SEP2020)	N/N
			Myalgia/ New muscle aches	1	10SEP2020	2/4	2	Yes		NA	R (13SEP2020)	N/N
		VASC	Hot flush/ Hot Flashes	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	1/5	1	Yes		NA	R (05OCT2020)	N/N
		SKIN	Hyperhidrosis/ Sweating	2	01OCT2020	1/5	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C459100 1 1270 12701084	3^	UNC	DIVERTICULITIS@@/ Diverticulitis	2	01OCT2020	3/12	1	No	O	NA/TC	R (12OCT2020)	N/N
16-55/ C459100 1 1270 12701085	3^	INFEC	Acute sinusitis/ Acute Sinusitis	1	14SEP2020	5/14	2	No	O	NA/TCN	R (27SEP2020)	N/N
16-55/ C459100 1 1270 12701086	3^	GENRL	Injection site pain/ Injection Site Pain	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 1270 12701089	3^	IMMUN	Seasonal allergy/ Worsening seasonal allergies	2	15OCT2020	14/14	2	No	O	NA/TC	R (28OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1270 12701090	3^	GENRL	Chills/ Chills	1	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C459100 1 1270 12701097	3^	NERV	Headache/ Headache	1	11SEP2020	1/4	1	Yes		NA/TC	R (14SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	12SEP2020	2/11	2	Yes		NA	R (22SEP2020)	N/N
			Injection site pain/ Left arm pain at injection site	1	12SEP2020	2/3	1	Yes		NA/TC	R (14SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		NERV	Dizziness/ Dizziness	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Tendon disorder/ Cystic lesion in medial patellofemoral retinaculum	1	24SEP2020	14/C	1	No	O	NA	N	N/N
		INFEC	Otitis externa/ Right otitis externa	2	12OCT2020	11/11	1	No	O	NA/TC	R (22OCT2020)	N/N
			Otitis media/ Right otitis media	2	12OCT2020	11/11	1	No	O	NA/TC	R (22OCT2020)	N/N
16-55/ C459100 1 1270 12701107	3^	INFEC	Ophthalmic herpes zoster/ Right eye herpes zoster keratitis (worsening)	2	23OCT2020	19/C	1	No	O	NA/TC/TCN	N	N/N
16-55/ C459100	3^	GENRL	Chills/ Chills	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1270 12701119			Pain/ Body Aches	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Pyrexia/ Fever	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C459100 1 1270 12701121	3^	UNC	VERTIGO@@/ Vertigo	2	04NOV2020	21/9	1	No	O	NA	R (12NOV2020)	N/N
16-55/ C459100 1 1270 12701122	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C459100 1 1270 12701124	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/Y
16-55/ C459100 1 1270 12701128	3^	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		METAB	Decreased appetite/ Loss of appetite	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		UNC	FATIGUE@@/ Fatigue	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1270 12701129	3^	GENRL	Chills/ Chills	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
			Pain/ Body Aches	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 1270 12701132	3^	MUSC	Back pain/ Burning-like back pain (worsening)	1	23SEP2020	6/22	2	No	O	NA	R (14OCT2020)	N/N
			Neck pain/ Increased neck pain (worsening)	1	23SEP2020	6/22	2	No	O	NA	R (14OCT2020)	N/N
		PSYCH	Sleep disorder/ Sleep disturbance	1	23SEP2020	6/22	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C459100 1 1270 12701135	3^	EAR	Eustachian tube dysfunction/ Left eustachian tube dysfunction	1	02OCT2020	15/27	1	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C459100 1 1270 12701137	3^	UNC	ELEVATED LOW-DENSITY LIPOPROTEIN@@/ Elevated low-density lipoprotein	1	23SEP2020	3/C	1	No	O	NA	N	N/N
		UNC	POSITIVE HERPES SIMPLEX VIRUS@@/ Positive Herpes Simplex Virus	1	24SEP2020	4/C	1			NA		N/N
		GASTR	Nausea/ Nausea	2	12OCT2020	1/3	2	Yes		NA/TC	R (14OCT2020)	N/N
		GENRL	Chills/ Chills	2	12OCT2020	1/2	2	Yes		NA	R (13OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ Fever	2	12OCT2020	1/3	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1270 12701142	3^	BLOOD	Lymphadenopathy/ Swollen left superficial cervical lymph node	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		UNC	FEVER@@/ Fever	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44441003	3^	GENRL	Pyrexia/ fever	2	13OCT2020	2/2	2	Yes		NA/TC	R (14OCT2020)	N/N
		NERV	Headache/ headache	2	13OCT2020	2/C	2	Yes		NA/TC	N	N/N
16-55/ C459100 1 4444 44441007	3^	INJ&P	Procedural haemorrhage/ Intraoperative hemorrhage during an elective laparoscopic ovarian cystectomy	1	03OCT2020	13/5	3	No	O	NA/TC	R (07OCT2020)	Y/N
		REPRO	Haemorrhagic ovarian cyst/ Hemorrhagic cyst of the right ovary	1	21OCT2020	31/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 4444 44441012	3^	INFEC	Oral herpes/ cold sore	2	02NOV2020	21/8	1	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C459100 1 4444 44441015	3^	MUSC	Myalgia/ left arm muscle pain	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441016	3^	NERV	Syncope/ Vasovagal syncope	2	13NOV2020	32/1	1	No	O	NA	R (13NOV2020)	N/N
16-55/ C459100 1 4444 44441017	3^	MUSC	Back pain/ Low back pain	2	29OCT2020	17/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 4444 44441028	3^	GENRL	Pyrexia/ Fever	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		NERV	Headache/ Headache	2	13OCT2020	2/1	2	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 4444 44441071	3^	GASTR	Diarrhoea/ Diarrhea	1	28SEP2020	8/3	1	No	O	NA/TCN	R (30SEP2020)	N/N
		GASTR	Abdominal pain upper/ Left upper quadrant abdominal pain	1	01OCT2020	11/20	2	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C459100 1 4444 44441095	3^	MUSC	Neck pain/ Neck pain	1	29SEP2020	9/3	1	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C459100	3^	RENAL	Dysuria/ dysuria	2	27OCT2020	15/14	1	No	O	NA/TC	R (09NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 4444 44441100	3^	GASTR	Toothache/ toothache	1	30SEP2020	10/7	1	No	O	NA/TC	R (06OCT2020)	N/N
1 4444 44441113		INFEC	Gingivitis/ Gingivitis	1	30SEP2020	10/7	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C459100 1 4444 44441121	3^	MUSC	Arthralgia/ Arthralgia of elbows and knees	2	14OCT2020	2/4	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44441125	3^	NERV	Headache/ headache	2	14OCT2020	2/1	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44441134	3^	MUSC	Back pain/ Worsening low back pain	1	03OCT2020	13/2	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 4444 44441144	3^	GASTR	Diarrhoea/ diarrhea	1	09OCT2020	19/2	2	No	O	NA	R (10OCT2020)	N/N
16-55/ C459100 1 4444 44441149	3^	MUSC	Arthralgia/ Left omalgia	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441154	3^	NERV	Headache/ Headache	1	22SEP2020	2/1	1	No	O	NA	R (22SEP2020)	N/N
		GASTR	Odynophagia/ Odynophagia	1	23SEP2020	3/1	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Chills/ Shaking chills	1	24SEP2020	4/1	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Pyrexia/ 38.0 C fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		METAB	Dyslipidaemia/ Dyslipidemia	1	07OCT2020	17/36	1	No	O	NA/TC	R (11NOV2020)	N/N
		VASC	Arteriosclerosis/ Atherosclerosis of vessels of the neck	1	07OCT2020	17/14	1	No	O	NA/TC	R (20OCT2020)	N/N
		GENRL	Pyrexia/ fever	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C459100 1 4444 44441160	3^	NEOPL	Lipoma/ worsening of soft tissue tumor resembling lipoma	1	01OCT2020	11/42	1	No	O	NA	R (11NOV2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/5	1	Yes		NA/TC	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 4444 44441166	3^	GENRL	Pyrexia/ Fever	2	14OCT2020	1/1	1	Yes		NA/TC	R (14OCT2020)	N/N
1 4444 44441176	3^	GENRL	Asthenia/ Asthenia	2	13OCT2020	2/3	2	Yes		NA/TC	R (15OCT2020)	N/N
1 4444 44441192			Injection site pain/ Injection site pain	2	13OCT2020	2/3	3	Yes		NA/TC	R (15OCT2020)	N/N
			Pyrexia/ Fever	2	13OCT2020	2/1	2	Yes		NA/TC	R (13OCT2020)	N/N
		MUSC	Muscular weakness/ arm weakness	2	13OCT2020	2/3	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 4444 44441203	3^	GENRL	Injection site pruritus/ Itching at injection site	2	14OCT2020	3/4	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44441209	3^	NERV	Headache/ Headache	1	25SEP2020	5/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C459100 1 4444 44441232	3^	GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441243	3^	GENRL	Pyrexia/ fever	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
		NERV	Headache/ headache	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44441249	3^	UNC	JAMMED RIGHT INGUINAL HERNIA@@/ Jammed Right inguinal hernia	1	05OCT2020	15/18	3	No	O	NA/TC/TCN	R (22OCT2020)	Y/N
16-55/ C459100 1 4444 44441268	3^	GASTR	Vomiting/ Vomits	1	12OCT2020	22/1	2	No	O	NA	R (12OCT2020)	N/N
16-55/ C459100 1 4444 44441275	3^	INFEC	Periodontitis/ periodontal infection	2	22OCT2020	10/15	1	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C459100 1 4444 44441300	3^	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
			Pyrexia/ low-grade fever	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ headache	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Pyrexia/ low-grade fever (37.5 C) with chills	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44441310	3^	MUSC	Muscle spasms/ Cramps in upper limbs	1	25SEP2020	4/14	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C459100 1 4444 44441321	3^	VASC	Varicose vein/ Worsening varicose veins in lower limbs	1	01OCT2020	10/30	1	No	O	NA	R (30OCT2020)	N/N
		GENRL	Pyrexia/ fever	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
		SKIN	Rash/ facial skin rash	2	22OCT2020	11/3	1	No	O	NA/TC	R (24OCT2020)	N/N
16-55/ C459100 1 4444 44441325	3^	GASTR	Gastritis/ Gastritis	2	21OCT2020	8/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 4444 44441326	3^	GENRL	Injection site pain/ Injection site pain	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 4444 44441330	3^	MUSC	Myalgia/ Generalized myalgia	2	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44441360	3^	REPRO	Testicular pain/ Pain in left testicle	1	24SEP2020	3/4	2	No	O	NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GASTR	Rectal haemorrhage/ Proctorrhagia	1	06OCT2020	15/2	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C459100 1 4444 44441361	3^	GENRL	Fatigue/ Tiredness	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ mild muscle pain.	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 4444 44441388	3^	INFEC	Periodontitis/ Periodontal infection	2	06NOV2020	25/7	1	No	O	NA/TCN	R (12NOV2020)	N/N
16-55/ C459100 1 4444 44441390	3^	GENRL	Injection site pain/ injection site pain	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
			Pyrexia/ fever	2	12OCT2020	1/2	1	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C459100 1 4444 44441400	3^	GENRL	Injection site pain/ injection site pain	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C459100 1 4444 44441402	3^	INJ&P	Ligament sprain/ Type 1 sprain on right ankle mild intensity	1	25SEP2020	4/20	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44441408	3^	GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	2	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441413	3^	GENRL	Chills/ Shaking chills	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 4444 44441432	3^	INFEC	Sinusitis/ Sinusitis	1	23SEP2020	2/7	2	No	O	NA	R (29SEP2020)	N/N
16-55/ C459100 1 4444 44441433	3^	MUSC	Arthralgia/ arthralgia	2	14OCT2020	2/2	2	No	O	NA/TC	R (15OCT2020)	N/N
			Myalgia/ myalgia	2	14OCT2020	2/2	2	No	O	NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 4444 44441435	3^	REPRO	Pelvic pain/ Pelvic pain	2	06NOV2020	24/C	1	No	O	NA	N	N/N
16-55/ C459100 1 4444 44441436	3^	GENRL	Pyrexia/ Fever	2	13OCT2020	2/1	2	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C459100 1 4444 44441442	3^	INFEC	Urinary tract infection/ Urinary infection	2	26OCT2020	14/8	1	No	O	NA/TC	R (02NOV2020)	N/N
16-55/ C459100 1 4444 44441452	3^	INJ&P	Animal bite/ Cat bite on right hand with a puncture wound.	2	22OCT2020	10/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441457	3 [^]	INFEC	Tooth infection/ Dental infection	2	07NOV2020	24/6	2	No	O	NA/TC/TCN	R (12NOV2020)	N/N
16-55/ C459100 1 4444 44441483	3 [^]	GENRL	Pyrexia/ fever	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 4444 44441487	3 [^]	NERV	Headache/ headache	1	24SEP2020	3/6	1	No	O	NA/TC	R (29SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44441494	3 [^]	GASTR	Gastritis/ Gastritis	1	24SEP2020	3/C	1	No	O	NA/TC	RG	N/N
		INV	Colonoscopy/ Colonoscopy	1	24SEP2020	3/1	1	No	O	NA	R (24SEP2020)	N/N
			Endoscopy upper gastrointestinal tract/ Upper Digestive Video Endoscopy	1	24SEP2020	3/1	1	No	O	NA	R (24SEP2020)	N/N
		NEOPL	Colon adenoma/ Colonic Polyp (Histologic analysis: tubular adenoma. Low-grade dysplasia)	1	24SEP2020	3/1	1	No	O	NA/TCN	R (24SEP2020)	N/N
		SURG	Polypectomy/ Polypectomy	1	24SEP2020	3/1	1	No	O	NA/TCN	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		PSYCH	Depression/ Worsening Depression	2	11NOV2020	30/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 4444 44441499	3^	MUSC	Myalgia/ GENERALIZED MYALGIA	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ myalgia	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 4444 44441503	3^	NERV	Migraine/ Worsening of migraine.	1	06OCT2020	15/4	2	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 4444 44441505	3^	GENRL	Injection site pain/ right arm pain at injection site	1	24SEP2020	3/1	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 4444 44441506	3^	GENRL	Asthenia/ Asthenia	1	03OCT2020	12/16	1	No	O	NA/TCN	R (18OCT2020)	N/N
16-55/ C459100 1 4444 44441514	3^	MUSC	Pain in extremity/ Left arm pain	2	12OCT2020	1/5	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Asthenia/ Asthenia	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441518	3^	GENRL	Pyrexia/ fever	2	13OCT2020	2/1	2	Yes		NA/TC	R (13OCT2020)	N/N
			Asthenia/ asthenia	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 4444 44441536	3^	NERV	Pyrexia/ fever	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
			Headache/ headache	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 4444 44441536	3^	GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44441539	3^	GENRL	Asthenia/ asthenia	2	17OCT2020	4/6	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 4444 44441542	3^	INFEC	Pyrexia/ Low grade fever	2	17OCT2020	4/2	1	Yes		NA/TC	R (18OCT2020)	N/N
			Tooth infection/ Dental infection	1	30SEP2020	8/11	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C459100 1 4444 44441544	3^	NERV	Headache/ Headache	1	01OCT2020	9/3	2	No	O	NA/TC	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441546	3^	INJ&P	Skin laceration/ Cutting skin lesion on left index finger	1	10OCT2020	18/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C459100 1 4444 44441553	3^	METAB	Insulin resistance/ Insulin resistance	1	30SEP2020	8/45	2	No	O	NA/TC	R (13NOV2020)	N/N
16-55/ C459100 1 4444 44441556	3^	GENRL	Pyrexia/ 38C Fever	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 4444 44441561	3^	GENRL	Injection site pain/ injection site Pain	2	15OCT2020	2/3	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44441572	3^	MUSC	Back pain/ low back pain	1	19OCT2020	27/3	1	No	O	NA	R (21OCT2020)	N/N
16-55/ C459100 1 4444 44441573	3^	GENRL	Asthenia/ Asthenia	1	23SEP2020	1/9	1	Yes		NA	R (01OCT2020)	N/N
			Chills/ chills	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Asthenia/ Asthenia	2	14OCT2020	1/6	1	Yes		NA	R (19OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Injection site pain/ Pain at the injection site (left arm)	2	14OCT2020	1/5	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 4444 44441577	3^	SURG	Endodontic procedure/ Root canal treatment	1	14OCT2020	22/1	1	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44441583	3^	GASTR	Toothache/ Right lower molar pain	2	30OCT2020	19/4	2	No	O	NA/TC	R (02NOV2020)	N/N
16-55/ C459100 1 4444 44441586	3^	INFEC	Tooth infection/ Odontogenic infection	1	02OCT2020	10/5	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C459100 1 4444 44441612	3^	GENRL	Pyrexia/ Fever	1	15OCT2020	23/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 4444 44441614	3^	MUSC	Myalgia/ right back myalgia	1	29SEP2020	7/4	1	No	O	NA/TC	R (02OCT2020)	N/N
16-55/ C459100 1 4444 44441616	3^	GASTR	Vomiting/ Vomiting	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
		NERV	Headache/ Headache	2	13OCT2020	2/3	2	Yes		NA/TC	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Pyrexia/ Fever	2	14OCT2020	3/1	2	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44441618	3^	MUSC	Intervertebral disc protrusion/ herniated disc	2	02NOV2020	20/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 4444 44441624	3^	INFEC	Acarodermatitis/ Scabies	1	07OCT2020	15/17	1	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C459100 1 4444 44441658	3^	GENRL	Pyrexia/ fever	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44441673	3^	GENRL	Pyrexia/ Fever	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	15OCT2020	2/4	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 4444 44441679	3^	GENRL	Application site pain/ pain at the application site	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		MUSC	Myalgia/ Generalized Myalgia	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		NERV	Headache/ Headache	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441680	3^	GENRL	Pyrexia/ fever	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 4444 44441682	3^	INJ&P	Joint injury/ Mild trauma to the left knee while doing regular physical activity	2	07NOV2020	25/1	1	No	O	NA	R (07NOV2020)	N/N
		MUSC	Arthralgia/ Left knee pain	2	07NOV2020	25/4	1	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C459100 1 4444 44441700	3^	GASTR	Diarrhoea/ Diarrhea	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
		GENRL	Illness/ Sickness	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 4444 44441716	3^	MUSC	Myalgia/ myalgia	2	14OCT2020	1/2	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 4444 44441719	3^	MUSC	Myalgia/ generalized myalgias	1	26SEP2020	4/3	2	Yes		NA/TC	R (28SEP2020)	N/N
16-55/ C459100 1 4444 44441725	3^	MUSC	Muscular weakness/ Generalized muscle weakness	1	09OCT2020	17/1	1	No	O	NA	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441733	3^	INJ&P	Myalgia/ Dorsal muscle pain	1	09OCT2020	17/1	1	No	O	NA/TC	R (09OCT2020)	N/N
			Head injury/ Head injury without loss of consciousness.	2	25OCT2020	12/8	1	No	O	NA/TC/TCN	R (01NOV2020)	N/N
16-55/ C459100 1 4444 44441735	3^	SKIN	Skin lesion/ indurated lesion on left arm	1	30SEP2020	8/18	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44441744	3^	NERV	Headache/ intermittent headache	1	24SEP2020	2/22	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 4444 44441746	3^	GENRL	Vaccination site oedema/ Edema at the vaccine application site	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 4444 44441748	3^	GASTR	Oesophageal food impaction/ esophageal impaction with food	1	28SEP2020	6/2	3	No	O	NA/TCN	R (29SEP2020)	Y/N
16-55/ C459100 1 4444 44441756	3^	GASTR	Nausea/ Nausea	1	24SEP2020	2/4	2	Yes		NA	R (27SEP2020)	N/N
		GENRL	Pyrexia/ Fever	1	24SEP2020	2/4	2	Yes		NA/TC	R (27SEP2020)	N/N
		MUSC	Myalgia/ Generalized myalgia	1	24SEP2020	2/4	2	Yes		NA/TC	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GASTR	Abdominal pain upper/ epigastralgia	1	11OCT2020	19/2	1	No	O	NA/TC	R (12OCT2020)	N/N
		MUSC	Neck pain/ cervicalgia	1	11OCT2020	19/3	2	No	O	NA	R (13OCT2020)	N/N
		MUSC	Arthralgia/ Right knee pain	2	04NOV2020	21/8	2	No	O	NA/TC	R (11NOV2020)	N/N
16-55/ C459100 1 4444 44441761	3^	GENRL	Application site rash/ Rash in the arm contralateral to the application of the research product	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C459100 1 4444 44441767	3^	GENRL	Pyrexia/ fever	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 4444 44441785	3^	GASTR	Vomiting/ Vomiting, 2 episodes	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Pyrexia/ FEVER	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 4444 44441788	3^	MUSC	Muscle contracture/ cervical contracture	2	01NOV2020	20/C	1	No	O	NA/TCN	RG	N/N
16-55/ C459100 1 4444 44441796	3^	GENRL	Pyrexia/ Fever	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441797	3^	GENRL	Pyrexia/ Fever	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 4444 44441801	3^	GENRL	Chest pain/ chest pain	2	28OCT2020	15/3	2	No	O	NA/TC	R (30OCT2020)	N/N
		VASC	Diastolic hypertension/ Diastolic arterial hypertension	2	29OCT2020	16/C	1	No	O	NA	N	N/N
		GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux	2	03NOV2020	21/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 4444 44441808	3^	INFEC	Tooth infection/ odontogenic infection	2	07NOV2020	24/7	1	No	O	NA/TC	R (13NOV2020)	N/N
16-55/ C459100 1 4444 44441810	3^	GENRL	Pyrexia/ FEVER	1	28SEP2020	4/2	2	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C459100 1 4444 44441815	3^	GASTR	Diarrhoea/ diarrhea	2	17OCT2020	3/2	1	Yes		NA	R (18OCT2020)	N/N
			Vomiting/ Vomits.	2	17OCT2020	3/2	2	Yes		NA/TC	R (18OCT2020)	N/N
		NERV	Headache/ Headache	2	17OCT2020	3/4	1	Yes		NA	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441824	3^	MUSC	Arthralgia/ Left shoulder pain	1	26SEP2020	2/24	1	No	O	NA	R (19OCT2020)	N/N
16-55/ C459100 1 4444 44441825	3^	MUSC	Back pain/ Back pain	1	11OCT2020	17/29	1	No	O	NA/TC	R (08NOV2020)	N/N
			Neck pain/ CERVICALGIA	1	11OCT2020	17/29	1	No	O	NA/TC	R (08NOV2020)	N/N
		MUSC	Back pain/ LUMBALGIA	1	26OCT2020	32/14	1	No	O	NA	R (08NOV2020)	N/N
16-55/ C459100 1 4444 44441840	3^	GENRL	Pyrexia/ Fever	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44441854	3^	GENRL	Fatigue/ FATIGUE	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
			Injection site pain/ injection site pain	2	16OCT2020	2/5	1	Yes		NA	R (20OCT2020)	N/N
		MUSC	Myalgia/ Myalgia generalized	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
		NERV	Headache/ Headache	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100	3^	GENRL	Asthenia/ Asthenia	2	16OCT2020	1/5	1	Yes		NA	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 4444 44441859		MUSC	Myalgia/ Myalgia	2	16OCT2020	1/5	1	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C459100 1 4444 44441861	3^	GENRL	Fatigue/ FATIGUE	2	16OCT2020	2/3	2	Yes		NA	R (18OCT2020)	N/N
			Injection site pain/ Injection site pain.	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
			Pyrexia/ Fever	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
		MUSC	Myalgia/ MYALGIAS	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
		NERV	Headache/ Headache	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 4444 44441872	3^	NERV	Headache/ headache	1	07OCT2020	13/3	1	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 4444 44441874	3^	NERV	Headache/ headache	1	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C459100 1 4444 44441881	3^	MUSC	Back pain/ Back pain	2	05NOV2020	23/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441896	3^	GENRL	Pyrexia/ Fever	2	17OCT2020	3/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 4444 44441900	3^	GENRL	Pyrexia/ Fever	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 4444 44441903	3^	MUSC	Myalgia/ Myalgia	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 4444 44441909	3^	SKIN	Dermatitis/ worsening of preauricular dermatitis*		25SEP2020	1/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 4444 44441910	3^	GENRL	Pyrexia/ Fever	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 4444 44441916	3^	MUSC	Muscle contracture/ Cervical contracture	1	02OCT2020	8/3	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C459100 1 4444 44441933	3^	GENRL	Axillary pain/ pain in right armpit	1	13OCT2020	19/3	1	No	O	NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44441934	3^	INFEC	Urinary tract infection/ Lower urinary tract infection	2	11NOV2020	28/C	1	No	CND	NA/TC	RG	N/N
16-55/ C459100 1 4444 44441949	3^	NERV	Paraesthesia/ Paresthesia in the anterior aspect of the left thigh	2	11NOV2020	29/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 4444 44441953	3^	PSYCH	Anxiety disorder/ Anxiety disorder	1	10OCT2020	16/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 4444 44441955	3^	GASTR	Gastritis/ Gastritis	1	04OCT2020	10/14	1	No	O	NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44441963	3^	GENRL	Asthenia/ asthenia	2	17OCT2020	2/4	1	Yes		NA/TC	R (20OCT2020)	N/N
			Pyrexia/ fever	2	17OCT2020	2/4	1	Yes		NA/TC	R (20OCT2020)	N/N
		NERV	Headache/ headache	2	17OCT2020	2/4	1	Yes		NA/TC	R (20OCT2020)	N/N
		NERV	Tremor/ BOTH HANDS FINE TREMOR	2	19OCT2020	4/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 4444 44441965	3^	GENRL	Asthenia/ Asthenia	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ Fever	2	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 4444 44441967	3^	SURG	Wisdom teeth removal/ Retained wisdom tooth extraction	1	09OCT2020	15/1	1	No	CND	NA	R (09OCT2020)	N/N
16-55/ C459100 1 4444 44441979	3^	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY*		05SEP2020	-20/C		No	O	P	UNK	N/N
16-55/ C459100 1 4444 44441988	3^	INFEC	Diverticulitis/ Diverticulitis	1	30SEP2020	6/22	2	No	O	NA/TC/TCN	R (21OCT2020)	N/N
16-55/ C459100 1 4444 44442009	3^	BLOOD	Lymphadenopathy/ left axillary adenopathy	2	15OCT2020	2/4	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 4444 44442032	3^	MUSC	Arthralgia/ Worsening of Hands arthralgia episode	1	04OCT2020	10/27	1	No	O	NA	R (30OCT2020)	N/N
16-55/ C459100 1 4444 44442033	3^	GENRL	Pyrexia/ fever	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100	3^	GENRL	Injection site erythema/ injection site erythema	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 4444 44442035			Pyrexia/ Fever	2	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N
		MUSC	Myalgia/ generalized Muscle pain	2	17OCT2020	2/C	1	Yes		NA	RG	N/N
		NERV	Headache/ Headache	2	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N
16-55/ C459100 1 4444 44442037	3^	NERV	Headache/ Headache	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44442047	3^	GENRL	Pyrexia/ fever	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
		NERV	Headache/ headache	2	18OCT2020	3/2	1	Yes		NA/TC	R (19OCT2020)	N/N
16-55/ C459100 1 4444 44442050	3^	GENRL	Asthenia/ Asthenia	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
			Pyrexia/ Fever	2	16OCT2020	1/3	2	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 4444 44442053	3^	INFEC	Tonsillitis bacterial/ Bacterial tonsillitis	1	02OCT2020	8/8	1	No	O	NA/TC	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44442062	3^	GENRL	Pyrexia/ fever	2	15OCT2020	1/1	1	Yes		NA/TC	R (15OCT2020)	N/N
		REPRO	Metrorrhagia/ mild metrorrhagia	2	16OCT2020	2/C	1	No	O	NA	N	N/N
16-55/ C459100 1 4444 44442071	3^	INFEC	Tooth infection/ odontogenic infection	1	10OCT2020	14/3	1	No	O	NA/TC	R (12OCT2020)	N/N
16-55/ C459100 1 4444 44442081	3^	GASTR	Constipation/ Constipation	1	28SEP2020	2/19	1	No	O	NA	R (16OCT2020)	N/N
16-55/ C459100 1 4444 44442084	3^	NERV	Sciatica/ lumbosciatalgia	1	07OCT2020	11/3	2	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C459100 1 4444 44442102	3^	GENRL	Pyrexia/ fever	2	16OCT2020	1/2	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44442105	3^	GENRL	Chills/ shaking chills	1	27SEP2020	1/2	2	Yes		NA/TC	R (28SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	27SEP2020	1/3	2	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C459100	3^	MUSC	Myalgia/ generalized myalgia	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 4444 44442106	3^	EYE	Conjunctivitis allergic/ worsening of allergic conjunctivitis	1	01OCT2020	5/6	1	No	O	NA	R (06OCT2020)	N/N
1 4444 44442113	3^	NERV	Headache/ headache	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
1 4444 44442117	3^	MUSC	Back pain/ Lumbar pain	2	13NOV2020	30/1	1	No	O	NA/TC	R (13NOV2020)	N/N
1 4444 44442119	3^	GENRL	Injection site pain/ Pain at injection site	2	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
		MUSC	Arthralgia/ generalized arthralgia	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
		NERV	Headache/ headache	2	17OCT2020	2/1	2	Yes		NA/TC	R (17OCT2020)	N/N
1 4444 44442135	3^	GENRL	Pyrexia/ fever of 38 degrees Celsius	2	15OCT2020	1/2	1	Yes		NA/TCN	R (16OCT2020)	N/N
		GENRL	Injection site swelling/ injection site swelling	2	16OCT2020	2/6	1	Yes		NA/TC	R (21OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44442146	3^	GENRL	Pyrexia/ fever	2	17OCT2020	2/3	2	Yes		NA/TC/TCN	R (19OCT2020)	N/N
16-55/ C459100 1 4444 44442154	3^	GENRL	Pyrexia/ low grade fever	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
		NERV	Headache/ headache	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44442159	3^	MUSC	Myalgia/ myalgia.	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
		NERV	Headache/ headache.	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 4444 44442160	3^	INFEC	Vaginal infection/ vaginal infection	2	11NOV2020	28/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 1 4444 44442163	3^	MUSC	Back pain/ back pain	2	16OCT2020	1/C	1	No	O	NA	RG	N/N
		GENRL	Pyrexia/ fever 39.2	2	17OCT2020	2/1	2	No	O	NA/TC/TCN	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44442171	3^	GENRL	Asthenia/ Asthenia	2	17OCT2020	2/4	2	Yes		NA/TC	R (20OCT2020)	N/N
			Pyrexia/ Fever	2	17OCT2020	2/1	3	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44442182	3^	GENRL	Pyrexia/ Fever	2	16OCT2020	1/2	1	Yes		NA/TCN	R (17OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44442193	3^	GENRL	Injection site pain/ Pain at injection site	1	27SEP2020	1/16	1	Yes		NA	R (12OCT2020)	N/Y
		GENRL	Asthenia/ Asthenia	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
			Injection site pain/ Right arm pain at the injection site of the research product	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44442203	3^	MUSC	Myalgia/ Myalgia	2	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N
		NERV	Dizziness/ Dizziness	2	09NOV2020	25/1	1	No	O	NA	R (09NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44442211	3^	INJ&P	Exposure during pregnancy/ Exposure during pregnancy (partner)	1	27SEP2020	1/C		No	O	NA	UNK	N/N
16-55/ C459100 1 4444 44442215	3^	NERV	Headache/ headache	2	16OCT2020	2/6	2	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 1 4444 44442226	3^	INFEC	Paronychia/ Periungual infection of the index finger	2	09NOV2020	26/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 4444 44442230	3^	GENRL	Pyrexia/ Isolated feverish record	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
		MUSC	Myalgia/ generalized myalgia	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44442232	3^	MUSC	Back pain/ Low back pain	1	12OCT2020	16/2	2	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C459100 1 4444 44442237	3^	MUSC	Pain in extremity/ Pain in upper left limb	2	15OCT2020	1/1	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C459100 1 4444 44442241	3^	NERV	Headache/ headache	2	18OCT2020	4/1	1	No	O	NA/TC/TCN	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44442274	3^	MUSC	Back pain/ back pain	1	13OCT2020	17/2	2	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44442278	3^	GENRL	Pyrexia/ Fever	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44442281	3^	GASTR	Toothache/ Odontalgia	1	10OCT2020	14/5	1	No	O	NA/TC	R (14OCT2020)	N/N
		INFEC	Gingivitis/ gingivitis	1	10OCT2020	14/5	1	No	O	NA/TC	R (14OCT2020)	N/N
			Tooth infection/ odontogenic infection	1	10OCT2020	14/5	1	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 4444 44442299	3^	GENRL	Vaccination site pain/ Post vaccination injection site pain.	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 4444 44442304	3^	METAB	Hyperglycaemia/ hyperglycemia	2	29OCT2020	15/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 4444 44442306	3^	MUSC	Myalgia/ Myalgia	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 4444 44442317	3^	NERV	Headache/ Headache with mild retro ocular pain	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 4444 44442317	3^	GENRL	Injection site pain/ pain at the injection site	2	16OCT2020	1/1	1	Yes		NA/TC	R (16OCT2020)	N/N
>55/ C459100 1 1001 10011099	2^	GENRL	Pyrexia/ fever	2	16OCT2020	1/1	1	Yes		NA/TC	R (16OCT2020)	N/N
>55/ C459100 1 1001 10011099	2^	GENRL	Chills/ Chills	1	15AUG2020	17/2	1	No	O	NA	R (16AUG2020)	N/N
>55/ C459100 1 1001 10011100	2^	SKIN	Dermatitis contact/ poison ivy	1	11AUG2020	13/21	2	No	O	NA/TC	R (31AUG2020)	N/N
>55/ C459100 1 1001 10011110	3^	SKIN	Dermatitis/ Dermatitis of trunk	2	25AUG2020	8/10	2	No	O	NA/TC	R (03SEP2020)	N/N
>55/ C459100 1 1001 10011110	3^	VASC	Raynaud's phenomenon/ exacerbation of raynaud's disease	2	02SEP2020	13/C	1	No	O	NA	N	N/N
>55/ C459100 1 1001 10011114	3^	GASTR	Gingival discomfort/ gum irritation	1	17AUG2020	15/2	1	Yes		NA/TC	R (18AUG2020)	N/N
>55/ C459100	3^	EAR	Vertigo/ exacerbation of vertigo	2	25AUG2020	2/7	1	Yes		NA	R (31AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1001 10011118 >55/ C459100	3^	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	2	10SEP2020	17/11	1	No	O	NA	R (20SEP2020)	N/N
1 1001 10011121 >55/ C459100	3^	EYE	Cataract/ worsening bilateral cataracts	1	2020	1/C	2	No	O	NA	RG	N/N
1 1001 10011133		GASTR	Nausea/ Nausea	1	22AUG2020	18/2	1	No	O	NA/TC	R (23AUG2020)	N/N
		EYE	Cataract/ Worsened cataract right eye	2	09NOV2020	75/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1001 10011142	3^	GASTR	Diarrhoea/ diarrhea	2	01SEP2020	8/3	1	Yes		NA	R (03SEP2020)	N/N
>55/ C459100 1 1001 10011144	3^	GENRL	Injection site discomfort/ injection site discomfort	2	07SEP2020	11/C	1	Yes		NA	N	N/N
>55/ C459100 1 1001 10011147	3^	MUSC	Osteoarthritis/ Exacerbation of degenerative joint disease	2	31AUG2020	4/C	1	No	O	NA	N	N/N
>55/ C459100	3^	GENRL	Injection site pain/ muscle tenderness at injection site	2	04SEP2020	8/8	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1001 10011148 >55/ C459100 1 1003 10031091	2^	INJ&P	Contusion/ Bruising on the upper left arm deltoid region	1	05AUG2020	10/28	1	Yes		NA	R (01SEP2020)	N/N
>55/ C459100 1 1003 10031092	2^	INJ&P	Tendon rupture/ Torn Lateral Epicondyle tendon	1	09AUG2020	13/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1003 10031099	2^	GENRL	Injection site swelling/ Swelling at injection site	1	31JUL2020	4/10	1	Yes		NA	R (09AUG2020)	N/N
>55/ C459100 1 1003 10031105	2^	GASTR	Odynophagia/ occasional odynophagia	1	12AUG2020	15/6	1	No	O	NA	R (17AUG2020)	N/N
		MUSC	Neck pain/ Left sided neck pain	1	12AUG2020	15/6	1	No	O	NA	R (17AUG2020)	N/N
>55/ C459100 1 1003 10031107	2^	GASTR	Diarrhoea/ Diarrhea	1	05AUG2020	8/2	1	No	O	NA	R (06AUG2020)	N/N
>55/ C459100 1 1003 10031109	2^	INJ&P	Muscle rupture/ Torn Right Bicep Muscle	1	13AUG2020	15/15	2	No	O	NA	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1003 10031113	2^	RESP	Interstitial lung disease/ worsening of interstitial lung disease	2	17OCT2020	59/C	4	No	O	NA/TC/TCN	RG	Y/N
		MUSC	Scleroderma/ possible scleroderma	2	20OCT2020	62/C	3	No	O	NA/TC/TCN	RG	Y/N
>55/ C459100 1 1003 10031120	3^	INFEC	Diverticulitis/ Possible Flare Up of Diverticulitis	1	11AUG2020	12/2	1	No	O	NA/TC	R (12AUG2020)	N/N
>55/ C459100 1 1003 10031130	3^	INJ&P	Skin laceration/ L middle finger sliced while fixing food	1	08AUG2020	6/7	1	No	O	NA/TC	R (14AUG2020)	N/N
>55/ C459100 1 1003 10031131	3^	VASC	Hypertension/ worsening of hypertension*		03AUG2020	1/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1003 10031135	3^	MUSC	Muscular weakness/ episodic muscle weakness arm	2	19OCT2020	57/C	1	No	O	NA	N	N/N
>55/ C459100 1 1003 10031139	3^	EAR	Vertigo positional/ worsening of benign paroxysmal positional vertigo	1	12AUG2020	9/27	3	No	O	NA/TC	R (07SEP2020)	N/N
		SKIN	Dermatitis contact/ poison ivy - Righ arm, both hands and legs	1	22AUG2020	19/11	2	No	O	NA/TC	R (01SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1003 10031149	3^	GASTR	Small intestinal obstruction/ small bowel obstruction	1	08AUG2020	4/3	4	No	O	NA/TC/TCN	R (10AUG2020)	Y/N
>55/ C459100 1 1003 10031167	3^	GENRL	Pyrexia/ Low Grade Fever - 100.0F	1	08AUG2020	2/1	1	Yes		NA/TC	R (08AUG2020)	N/N
		MUSC	Myalgia/ Myalgia	1	08AUG2020	2/C	2	Yes		NA/TC	N	N/N
>55/ C459100 1 1003 10031182	3^	GASTR	Inguinal hernia/ right inguinal hernia	1	25AUG2020	15/32	2	No	O	NA/TCN	R (25SEP2020)	N/N
		SURG	Inguinal hernia repair/ laparoscopic right inguinal hernia repair	2	24SEP2020	24/2	3	No	O	NA/TC/TCN	R (25SEP2020)	N/N
>55/ C459100 1 1003 10031195	3^	INFEC	Diverticulitis/ Diverticulitis	2	28SEP2020	26/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1003 10031208	3^	GASTR	Abdominal rigidity/ Abdominal Spasms	2	16SEP2020	13/C	2	No	O	NA/TC	RG	N/N
		MUSC	Muscle spasms/ Back Pain Spasms	2	16SEP2020	13/C	2	No	O	NA/TC	RG	N/N
		GASTR	Constipation/ constipation	2	21SEP2020	18/C	3	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1005 10051006	3^	INJ&P	Arthropod bite/ Tick bite	1	28AUG2020	19/1	1	No	CD	NA	R (28AUG2020)	N/N
>55/ C459100 1 1005 10051011	3^	INJ&P	Arthropod bite/ TICK BITE	1	12AUG2020	3/15	1	No	O	NA/TC	R (26AUG2020)	N/N
		MUSC	Pain in extremity/ LEG PAIN	2	01SEP2020	2/2	1	Yes		NA/TC	R (02SEP2020)	N/N
>55/ C459100 1 1005 10051021	3^	GASTR	Parotid duct obstruction/ LEFT PAROTID GLAND OBSTRUCTION	2	05SEP2020	6/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1005 10051022	3^	GASTR	Diarrhoea/ DIARRHEA	1	17AUG2020	7/2	1	No	O	NA	R (18AUG2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	06SEP2020	7/4	1	Yes		NA/TC	R (09SEP2020)	N/N
>55/ C459100 1 1005 10051023	3^	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	22SEP2020	23/5	1	No	O	NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1005 10051025	3^	GENRL	Fatigue/ FATIGUE	2	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
		PSYCH	Irritability/ IRRITABLE	2	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1005 10051069	3^	NEOPL	Breast cancer/ LEFT BREAST CANCER	2	04SEP2020	3/C	1	No	O	NA	N	Y/N
>55/ C459100 1 1005 10051078	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
		SKIN	Dermal cyst/ CYST ON LOWER BACK	1	22AUG2020	4/12	1	No	O	NA/TC	R (02SEP2020)	N/N
>55/ C459100 1 1005 10051083	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	2/2	1	Yes		NA/TC	R (21AUG2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		GASTR	Nausea/ NAUSEA	2	14SEP2020	6/2	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	14SEP2020	6/2	2	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	14SEP2020	6/2	2	Yes		NA/TC	R (15SEP2020)	N/N
>55/ C459100 1 1005 10051088	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1005 10051090	3^	GENRL	Pyrexia/ FEVER 102F	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
		RESP	Oropharyngeal pain/ SORE THROAT	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
		RESP	Cough/ COUGH	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1005 10051091	3^	GENRL	Oropharyngeal pain/ SORE THROAT	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	1/2	2	Yes		NA/TC	R (21AUG2020)	N/N
>55/ C459100 1 1005 10051098	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
>55/ C459100 1 1005 10051102	3^	GENRL	Fatigue/ FATIGUE	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1005 10051103	3^	PSYCH	Abnormal dreams/ VIVID DREAMS	1	23AUG2020	4/2	1	Yes		NA	R (24AUG2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Injection site erythema/ INJECTION SITE REDNESS	2	13SEP2020	4/1	1	Yes		NA	R (13SEP2020)	N/N
			Injection site warmth/ WARMTH AT INJECTION SITE	2	13SEP2020	4/1	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Injection site pruritus/ INJECTION SITE PRURITUS	2	14SEP2020	5/C	1	Yes		NA	N	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
		GASTR	Nausea/ NAUSEA	2	09SEP2020	1/C	2	Yes		NA	N	N/N
		GENRL	Fatigue/ FATIGUE	2	09SEP2020	1/C	2	Yes		NA	N	N/N
			Pyrexia/ FEVER	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
MUSC	Arthralgia/ GENERALIZED JOINT PAIN	2	09SEP2020	1/C	2	Yes		NA	N	N/N		
	Myalgia/ GENERALIZED MYALGIA	2	09SEP2020	1/C	2	Yes		NA	N	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ HEADACHE	2	09SEP2020	1/C	3	Yes		NA/TC	N	N/N
>55/ C459100 1 1005 10051104	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
		GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N
		MUSC	Myalgia/ MYALGIA	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1005 10051114	3^	GENRL	Chills/ CHILLS	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
			Fatigue/ FATIGUE	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
>55/ C459100 1 1005 10051116	3^	GENRL	Injection site pain/ soreness at injection site	1	21AUG2020	1/3	1	Yes		NA/TC	R (23AUG2020)	N/N
		INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	21SEP2020	12/11	2	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1005 10051124	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	16SEP2020	1/C	1	Yes		NA	N	N/N
		GENRL	Chills/ CHILLS	2	17SEP2020	2/C	1	Yes		NA	N	N/N
			Pyrexia/ FEVER 101F	2	17SEP2020	2/C	1	Yes		NA	N	N/N
>55/ C459100 1 1005 10051130	3^	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	25AUG2020	2/8	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ FEVER 100.5	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1005 10051131	3^	GENRL	Injection site pain/ Injection site pain	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1005 10051136	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	16SEP2020	2/1	2	Yes		NA/TC	R (16SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1005 10051137 >55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	25AUG2020	1/2	2	Yes		NA/TC	R (26AUG2020)	N/N
1 1005 10051138		GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	16SEP2020	1/3	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1005 10051152	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
>55/ C459100 1 1005 10051156	3^	RESP	Paranasal sinus discomfort/ SINUS PRESSURE	2	14OCT2020	29/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1005 10051158	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
			Malaise/ MALAISE	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1005 10051160	3^	GENRL	Fatigue/ FATIGUE	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1005 10051162	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
>55/ C459100 1 1005 10051173	3^	GENRL	Injection site pain/ INJECTION SITE PAIN IN LEFT ARM	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
			Injection site pain/ INJECTION SITE TENDERNESS IN LEFT ARM	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1005 10051177	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Malaise/ MALAISE	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
		NERV	Headache/ HEADACHE	1	12SEP2020	17/2	1	No	O	NA/TC	R (13SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	16SEP2020	1/C	1	Yes		NA	N	N/N
		GENRL	Fatigue/ FATIGUE	2	17SEP2020	2/C	2	Yes		NA	N	N/N
			Malaise/ MALAISE	2	17SEP2020	2/C	2	Yes		NA	N	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ GENERALIZED MYALGIA	2	17SEP2020	2/C	2	Yes		NA	N	N/N
>55/ C459100 1 1005 10051180	3^	GENRL	Fatigue/ FATIGUE	2	19SEP2020	3/2	1	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ MYALGIA	2	19SEP2020	3/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1005 10051185	3^	INFEC	Tooth infection/ DENTAL INFECTION	1	09SEP2020	10/C	2	No	O	NA/TC	N	N/N
		INFEC	Urinary tract infection/ URINARY TRACT INFECTION	1	17SEP2020	18/C	2	No	O	NA	N	N/N
>55/ C459100 1 1005 10051186	3^	GENRL	Fatigue/ FATIGUE	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
>55/ C459100 1 1005 10051191	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	21SEP2020	1/5	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Fatigue/ FATIGUE	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1005 10051193	3^	INFE	Gastroenteritis/ GASTROENTERITIS	1	18SEP2020	17/2	2	No	O	NA	R (19SEP2020)	N/N
>55/ C459100 1 1005 10051201	3^	MUSC	Myalgia/ GENERALIZED MYALGIA	1	05SEP2020	3/8	2	Yes		NA	R (12SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	05SEP2020	3/2	1	Yes		NA	R (06SEP2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	2	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	22SEP2020	1/5	2	Yes		NA/TC	R (26SEP2020)	N/N
		MUSC	Arthralgia/ KNEE PAIN	2	29SEP2020	8/C	1	No	O	NA	N	N/N
>55/ C459100 1 1005 10051204	3^	GENRL	Fatigue/ FATIGUE	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	22SEP2020	1/6	2	Yes		NA	R (27SEP2020)	N/N
			Pyrexia/ FEVER 100.5	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ MYALGIA	2	22SEP2020	1/2	2	Yes		NA/TC	R (23SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ HEADACHE	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1005 10051206	3^	GENRL	Fatigue/ FATIGUE	2	18OCT2020	25/4	2	No	O	NA	R (21OCT2020)	N/N
>55/ C459100 1 1005 10051211	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1005 10051214	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	2/4	2	Yes		NA	R (07SEP2020)	N/N
		GENRL	Facial pain/ FACIAL TENDERNESS	1	06SEP2020	4/11	2	No	O	P/TC	R (16SEP2020)	N/N
			Swelling face/ FACIAL SWELLING	1	06SEP2020	4/11	2	No	O	P/TC	R (16SEP2020)	N/N
		INFEC	Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION	1	06SEP2020	4/11	2	No	O	NA/TC	R (16SEP2020)	N/N
>55/ C459100 1 1006 10061006	3^	SURG	Postoperative care/ RIGHT CATARACT REPAIR AFTERCARE	1	14AUG2020	5/C	1	No	O	NA/TC	RG	N/N
>55/ C459100	3^	CARD	Angina pectoris/ ANGINA	1	21AUG2020	10/7	2	No	O	NA/TCN	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1006 10061020		CARD	Acute myocardial infarction/ NON-ST ELEVATED MYOCARDIAL INFARCTION	1	25AUG2020	14/3	3	No	O	NA/TC/TCN	R (27AUG2020)	N/N
			Coronary artery occlusion/ CORONARY ARTERY OCCLUSION	1	25AUG2020	14/3	4	No	O	P/TC/TCN/W	R (27AUG2020)	Y/N
			Mitral valve incompetence/ MITRAL VALVE REGURGITATION	1	25AUG2020	14/3	3	No	O	NA/TCN	R (27AUG2020)	N/N
		RESP	Dyspnoea exertional/ DYSPNEA ON EXERTION	1	25AUG2020	14/3	2	No	O	NA/TCN	R (27AUG2020)	N/N
>55/ C459100 1 1006 10061025	3^	IMMUN	Seasonal allergy/ WORSENING SEASONAL ALLERGIES	1	30AUG2020	19/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1006 10061030	3^	INJ&P	Tooth fracture/ Broken Tooth	2	15SEP2020	13/C	2	No	O	NA/TC/TCN	RG	N/N
>55/ C459100 1 1006 10061097	3^	MUSC	Arthralgia/ BILATERAL HAND JOINT PAIN	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
			Muscular weakness/ LEFT LEG MUSCLE WEAKNESS	2	16SEP2020	2/3	3	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Hypoaesthesia/ LEFT LEG MUSCLE NUMBNESS	2	16SEP2020	2/3	3	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1006 10061098	3^	NERV	Headache/ Headache	1	24AUG2020	1/2	2	Yes		NA/TC	R (25AUG2020)	N/N
		INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	03OCT2020	19/10	3	No	O	NA/TC	R (12OCT2020)	N/N
		CARD	Atrial fibrillation/ ATRIAL FIBRILLATION INTERMITTENT	2	06OCT2020	22/7	2	No	CD	NA/TC/TCN	R (12OCT2020)	Y/N
>55/ C459100 1 1006 10061101	3^	GASTR	Vomiting/ VOMITING	1	26AUG2020	3/7	3	Yes		NA/TC	R (01SEP2020)	N/N
		GENRL	Chills/ CHILLS	1	26AUG2020	3/5	2	Yes		NA	R (30AUG2020)	N/N
		MUSC	Flank pain/ RIGHT FLANK PAIN	1	26AUG2020	3/5	3	Yes		NA/TC	R (30AUG2020)	N/N
>55/ C459100 1 1006 10061139	3^	INJ&P	Arthropod bite/ Spider Bite	2	19OCT2020	26/1	1	No	O	NA/TC	R (19OCT2020)	N/N
>55/ C459100 1 1006 10061149	3^	RESP	Rhinorrhoea/ Runny Nose	1	06OCT2020	21/8	1	No	O	NA/TC	R (13OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1006 10061158	3^	GENRL	Chills/ Chills	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
			Pyrexia/ Fever	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
		MUSC	Arthralgia/ Generalized Joint Aches	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
		NERV	Headache/ Headache	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
>55/ C459100 1 1007 10071081	2^	IMMUN	Seasonal allergy/ Exacerbation of Seasonal Allergies	2	20AUG2020	2/4	2	No	O	NA/TC	R (23AUG2020)	N/N
>55/ C459100 1 1007 10071101	2^	CARD	Cardiac arrest/ Cardiac Arrest	2	18OCT2020	60/4	4	No	O	NA/W	F (21OCT2020)	Y/N
>55/ C459100 1 1007 10071127	3^	MUSC	Pain in extremity/ Right foot pain	2	20SEP2020	26/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1007 10071128	3^	INJ&P	Fall/ Fall while running	1	12AUG2020	8/1	2	No	O	NA	R (12AUG2020)	N/N
			Humerus fracture/ humeral fracture	1	12AUG2020	8/51	2	No	O	NA/TC	R (01OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1007 10071144	3^	SKIN	Pruritus/ pruritus face, shoulder arms and torso	2	02SEP2020	7/1	2	No	O	NA/TC	R (02SEP2020)	N/N
		SKIN	Pruritus/ pruritic face, shoulder arms and torso	2	10SEP2020	15/1	2	No	O	NA/TC	R (10SEP2020)	N/N
>55/ C459100 1 1007 10071161	3^	PSYCH	Sleep disorder/ sleep disturbance	1	24AUG2020	15/4	1	No	O	NA/TC	R (27AUG2020)	N/N
		EYE	Vision blurred/ Right eye blurred vision	1	26AUG2020	17/C	2	No	O	NA	N	N/N
		METAB	Decreased appetite/ Loss of appetite	2	01SEP2020	2/29	2	No	O	NA	R (29SEP2020)	N/N
>55/ C459100 1 1007 10071174	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	17AUG2020	6/6	1	No	O	NA	R (22AUG2020)	N/N
>55/ C459100 1 1007 10071183	3^	GASTR	Nausea/ nausea	2	03SEP2020	1/2	2	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 1 1007 10071199	3^	GENRL	Chills/ chills	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
			Fatigue/ Fatigue	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1007 10071200	3^	GENRL	Chills/ chills	1	20AUG2020	4/2	1	Yes		NA	R (21AUG2020)	N/N	
			Fatigue/ fatigue	1	20AUG2020	4/2	1	Yes		NA	R (21AUG2020)	N/N	
			RESP	Throat irritation/ scratchy throat	1	20AUG2020	4/2	1	Yes		NA	R (21AUG2020)	N/N
			GENRL	Chills/ Chills	2	08SEP2020	1/3	1	Yes		NA/TCN	R (10SEP2020)	N/N
				Injection site pain/ Injection site pain	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N
			GENRL	Pyrexia/ Fever	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
			METAB	Polydipsia/ Polydipsia	2	09SEP2020	2/2	1	Yes		NA/TCN	R (10SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N		
>55/ C459100 1 1007 10071205	3^	GENRL	Injection site pain/ injection site soreness	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N	
			GENRL	Chills/ chills	1	08SEP2020	23/2	1	Yes		NA	R (09SEP2020)	N/N
				Fatigue/ fatigue	1	08SEP2020	23/2	1	Yes		NA	R (09SEP2020)	N/N
			GENRL	Injection site pain/ arm soreness at injection site	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1007 10071209	3^	METAB	Hypercholesterolaemia/ hypercholesteremia	2	22SEP2020	15/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1007 10071213	3^	GENRL	Injection site pain/ injection site soreness	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
		INFEC	Gingival abscess/ gum abscess	1	02SEP2020	17/30	2	No	O	NA/TC	R (01OCT2020)	N/N
		SURG	Apicectomy/ apicoectomy	1	01OCT2020	46/1	2	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1007 10071215	3^	GENRL	Injection site induration/ induration at injection site	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
>55/ C459100 1 1007 10071222	3^	GENRL	Induration/ Induration	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/Y
		SKIN	Ecchymosis/ Ecchymosis	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N
>55/ C459100 1 1007 10071242	3^	NERV	Headache/ Intermittent Headache	2	08OCT2020	29/2	1	No	O	NA/TC	R (09OCT2020)	N/N
>55/ C459100 1 1007 10071245	3^	GENRL	Fatigue/ fatigue	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Myalgia	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N
>55/ C459100 1 1007 10071255	3^	SKIN	Dermatitis contact/ Contact Dermatitis	1	29AUG2020	6/2	2	No	O	NA/TC	R (30AUG2020)	N/N
>55/ C459100 1 1007 10071257	3^	GENRL	Fatigue/ fatigue	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N
>55/ C459100 1 1007 10071259	3^	NERV	Headache/ headache	2	16SEP2020	1/3	1	No	O	NA	R (18SEP2020)	N/N
>55/ C459100 1 1007 10071260	3^	GENRL	Injection site pain/ injection site soreness	1	24AUG2020	1/2	2	Yes		NA/TC	R (25AUG2020)	N/N
>55/ C459100 1 1007 10071283	3^	GENRL	Chills/ chills	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
			Fatigue/ fatigue	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 1 1007 10071294	3^	GENRL	Injection site haematoma/ injection site hematoma	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/Y
		MUSC	Myalgia/ muscle soreness	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1008 10081050	3^	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	8/2	1	Yes		NA	R (16SEP2020)	N/N
		INFEC	Gastroenteritis/ Gastroenteritis	2	16SEP2020	9/2	1	No	O	NA	R (17SEP2020)	N/N
>55/ C459100 1 1008 10081062	3^	GENRL	Pain/ Body aches	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
>55/ C459100 1 1008 10081070	3^	GENRL	Chills/ chills	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ fever	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ headache	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1008 10081073	3^	GENRL	Fatigue/ fatigue	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
			Pain/ body aches	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Fatigue/ fatigue	2	11SEP2020	2/C	1	Yes		NA	N	N/N
>55/ C459100	3^	GENRL	Chills/ chills	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1008 10081082												
>55/ C459100	3^	RESP	Oropharyngeal pain/ Sore throat	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N
1 1008 10081083												
>55/ C459100	3^	GENRL	Chills/ Chills	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
1 1008 10081090												
			Fatigue/ Fatigue	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		INFECTION	Gastroenteritis/ Gastroenteritis	2	03OCT2020	19/2	1	No	O	NA	R (04OCT2020)	N/N
>55/ C459100	3^	GENRL	Chills/ chills	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
1 1008 10081094												
		GENRL	Chills/ chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
			Pain/ bodyaches	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
			Pyrexia/ fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ headache	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1008 10081100		MUSC	Myalgia/ Muscle aches	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1008 10081125	3^	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1008 10081131	3^	GENRL	Injection site erythema/ Grade 2 injection site redness	2	18SEP2020	2/3	2	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1008 10081157	3^	GENRL	Pain/ Body aches	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1008 10081164	3^	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ Injection site pain Left deltoid	2	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 1 1008 10081165	3^	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Injection site pain/ Injection site pain Left arm	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1008 10081168	3^	NERV	Headache/ Headache	2	29SEP2020	7/3	1	No	O	NA	R (01OCT2020)	N/N
>55/ C459100 1 1008 10081173	3^	GENRL	Chills/ Chills	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C459100 1 1008 10081174	3^	GENRL	Injection site pain/ Injection site pain left arm	2	24SEP2020	2/6	1	Yes		NA	R (29SEP2020)	N/N
>55/ C459100 1 1008 10081175	3^	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
			Pain/ Body aches	1	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N
			Pyrexia/ Fever	1	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Pain/ Body aches	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1008 10081182	3^	EYE	Keratitis/ Corneal inflammation left eye	1	17SEP2020	15/8	1	No	O	NA/TC	R (24SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1008 10081184	3^	NEOPL	Prostate cancer/ Prostate cancer	2	30SEP2020	7/C	2	No	O	NA	N	Y/N
>55/ C459100 1 1008 10081185	3^	GASTR	Diarrhoea/ Diarrhea	2	02OCT2020	8/1	1	No	O	NA	R (02OCT2020)	N/N
>55/ C459100 1 1008 10081186	3^	GENRL	Injection site pain/ Injection site pain left arm	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 1 1008 10081192	3^	GENRL	Chills/ Chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1008 10081208	3^	NERV GENRL	Fatigue/ Fatigue	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N	
			Pyrexia/ Fever	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N	
			Headache/ Headache	2	26SEP2020	2/2	1	Yes			NA	R (27SEP2020)	N/N
			Asthenia/ Weakness	2	02OCT2020	2/1	1	Yes			NA	R (02OCT2020)	N/N
			Chills/ Chills	2	02OCT2020	2/1	1	Yes			NA	R (02OCT2020)	N/N
>55/ C459100 1 1008 10081209	3^	NERV GENRL	Fatigue/ Fatigue	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N	
			Chills/ Chills	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N	
			Pain/ Body aches	2	30SEP2020	2/3	1	Yes			NA	R (02OCT2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	2/3	1	Yes			NA	R (02OCT2020)	N/N
>55/ C459100 1 1008 10081211	3^	NERV GENRL	Sciatica/ sciatica	1	16SEP2020	9/C	2	No	O	NA/TC	N	N/N	
			Chills/ Chills	2	30SEP2020	2/1	1	Yes			NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1008 10081222	3^	GASTR	Pain/ Body aches	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
			Vomiting/ Vomiting	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
			Chills/ Chills	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N
		NERV	Injection site pain/ Injection site pain	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
			Pain/ Body aches	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
			Headache/ Headache	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N
METAB	Decreased appetite/ Loss of appetite	2	30SEP2020	3/2	1	Yes		NA	R (01OCT2020)	N/N		
>55/ C459100 1 1008 10081226	3^	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ Injection site pain left deltoid	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Pain/ Body aches	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1008 10081228	3^	SKIN	Rash/ Rash extremities unknown etiology	1	11SEP2020	4/47	1	No	O	NA/TC	R (27OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1008 10081237	3^	GASTR	Diarrhoea/ Diarrhea	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
>55/ C459100 1 1008 10081242	3^	GENRL	Chills/ Chills	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Fatigue	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1008 10081246	3^	GENRL	Pyrexia/ Fever	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		NERV	Dizziness/ Dizziness	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1008 10081248	3^	GASTR	Diarrhoea/ Diarrhea	1	13SEP2020	5/2	1	Yes		NA	R (14SEP2020)	N/N
			Nausea/ Nausea	1	13SEP2020	5/2	1	Yes		NA	R (14SEP2020)	N/N
			Vomiting/ Vomiting	1	13SEP2020	5/2	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1008 10081250	3^	GENRL	Injection site pain/ Injection site pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Pyrexia/ Fever	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1008 10081252	3^	GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
>55/ C459100 1 1008 10081269	3^	GENRL	Chills/ Chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Fatigue	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
			Pain/ Body aches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1008 10081270	3^	GENRL	Chills/ Chills	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
			Pain/ Body aches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1008 10081298	3^	GENRL	Injection site pain/ Injection site pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
			Malaise/ Malaise	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
			Pain/ Body aches	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
>55/ C459100 1 1008 10081299	3^	GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
			Fatigue/ Fatigue	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
			Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
			NERV Headache/ Headache	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1008 10081303	3^	GENRL	Pain/ Body aches	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
>55/ C459100 1 1008 10081307	3^	GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
			Pain/ Body aches	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1008 10081309	3^	GASTR	Diarrhoea/ Diarrhea	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1008 10081318	3^	GENRL	Injection site pain/ Injection site pain	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1008 10081322	3^	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1008 10081332	3^	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
			Pain/ Body aches	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C459100 1 1008 10081335	3^	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1008 10081355	3^	GASTR	Diarrhoea/ Diarrhea	1	18SEP2020	3/3	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1008 10081363	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
			Pain/ Body aches	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ Headache	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1008 10081376	3^	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
>55/ C459100 1 1008 10081378	3^	GENRL	Chills/ Chills	1	23SEP2020	7/2	1	Yes		NA	R (24SEP2020)	N/N
		SKIN	Hyperhidrosis/ Sweating	1	23SEP2020	7/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1008 10081380	3^	GENRL	Injection site pain/ Injection site soreness	2	09OCT2020	2/6	1	Yes		NA	R (14OCT2020)	N/N
			Pyrexia/ Fever	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
>55/ C459100 1 1008 10081400	3^	INJ&P	Arthropod bite/ Tick bite	2	24OCT2020	17/14	1	No	O	NA/TC	R (06NOV2020)	N/N
>55/ C459100 1 1008 10081412	3^	GENRL	Fatigue/ Fatigue	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ Injection site pain	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Pain/ Body aches	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
			Injection site pain/ Injection site pain	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
			Pain/ Body aches	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
>55/ C459100	3^	NERV	Parosmia/ Olfactory disturbance	1	22SEP2020	1/C	1	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1008 10081443												
>55/ C459100 1 1008 10081454	3^	GASTR	Nausea/ Nausea	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
		GENRL	Chills/ Chills	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
		MUSC	Myalgia/ Muscles aches	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 1008 10081482	3^	GASTR	Diarrhoea/ Diarrhea	1	05OCT2020	13/1	1	No	O	NA	R (05OCT2020)	N/N
			Vomiting/ Vomiting	1	05OCT2020	13/1	1	No	O	NA	R (05OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	14OCT2020	1/C	1	Yes		NA	RG	N/N
>55/ C459100 1 1008 10081490	3^	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1008 10081495	3^	GENRL	Injection site pain/ Injection site pain	2	14OCT2020	1/8	1	Yes		NA	R (21OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1008 10081503	3^	GENRL	Pyrexia/ Fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 1008 10081511	3^	MUSC	Myalgia/ Muscle aches	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Pyrexia/ Fever	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 1 1008 10081526	3^	SKIN	Dermatitis contact/ Contact dermatitis	2	08NOV2020	25/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1008 10081531	3^	GENRL	Chills/ Chills	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
>55/ C459100 1 1008 10081550	3^		Injection site pain/ Injection site pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
		METAB	Decreased appetite/ Loss of appetite	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
>55/ C459100 1 1008 10081550	3^	GENRL	Chills/ chills	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pain/ bodyaches	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		PSYCH	Anxiety/ Anxiety	1	14OCT2020	16/C	2	No	O	NA/TCN	N	N/N
			Depression/ Depression	1	14OCT2020	16/C	2	No	O	NA/TCN	N	N/N
>55/ C459100 1 1008 10081564	3^	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
>55/ C459100 1 1008 10081566	3^	GENRL	Chills/ Chills	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
>55/ C459100 1 1008 10081571	3^	INFEC	Otitis externa/ Otitis externa Left ear	1	08OCT2020	2/8	1	No	O	NA/TC	R (15OCT2020)	N/N
>55/ C459100 1 1009 10091029	3^	INFEC	Skin infection/ skin infection right hand	2	18SEP2020	17/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1009 10091034	3^	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	1	14AUG2020	2/19	2	No	O	NA/TC	R (01SEP2020)	N/N
>55/ C459100 1 1009 10091041	3^	MUSC	Arthralgia/ Intermittent Bilateral Ankle Pain, Unspecified	2	07SEP2020	6/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1009 10091069	3^	GASTR	Diarrhoea/ DIARRHEA	1	19AUG2020	2/1	1	No	O	NA	R (19AUG2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1009 10091077	3^	GENRL	Fatigue/ fatigue	2	09SEP2020	2/4	1	Yes		NA	R (12SEP2020)	N/N
		MUSC	Myalgia/ generalized muscle soreness	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1009 10091089	3^	INJ&P	Skin laceration/ LEFT THUMB LACERATION	1	06SEP2020	18/18	2	No	O	NA/TC	R (23SEP2020)	N/N
		PSYCH	Depression/ Worsening of Depression	2	21OCT2020	15/C	3	No	O	NA	N	N/N
>55/ C459100 1 1009 10091135	3^	NEOPL	Intraductal proliferative breast lesion/ Right Breast Ductal Carcinoma In Situ	1	02SEP2020	3/C	1	No	O	NA	N	Y/N
		REPRO	Breast mass/ right breast lump	1	02SEP2020	3/C	1	No	O	NA	N	N/N
>55/ C459100	3^	INFEC	Cystitis/ CYSTITIS	2	06OCT2020	16/9	2	No	O	NA/TC	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1009 10091143 >55/ C459100 1 1009 10091154	3^	GASTR	Nausea/ nausea	1	04SEP2020	1/2	2	Yes		NA	R (05SEP2020)	N/N
		NERV	Headache/ headache	1	04SEP2020	1/2	3	Yes		NA/TC	R (05SEP2020)	N/N
		GENRL	Chills/ Chills	2	24SEP2020	2/C	1	Yes		NA	N	N/N
			Injection site pain/ soreness at injection site	2	24SEP2020	2/C	1	Yes		NA	N	N/N
>55/ C459100 1 1009 10091160	3^	INFEC	Urinary tract infection/ urinary tract infection	1	13SEP2020	6/10	2	No	O	NA/TC	R (22SEP2020)	N/N
>55/ C459100 1 1009 10091162	3^	GASTR	Toothache/ Toothache	1	20SEP2020	12/C	2	No	O	NA/TC	N	N/N
		INFEC	Oral herpes/ cold sore to mouth	2	12OCT2020	15/5	1	No	O	NA/TC	R (16OCT2020)	N/N
>55/ C459100 1 1009 10091190	3^	INFEC	Ear infection/ ear infection	1	10OCT2020	17/C	2	No	O	NA/TC	RG	N/N
>55/ C459100	3^	NERV	Headache/ Headache	2	01OCT2020	29/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1011 10111018		RESP	Nasal congestion/ Nasal Congestion	2	01OCT2020	29/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1011 10111029	3^	INFEC	Appendicitis perforated/ Perforated Appendicitis	2	12SEP2020	13/4	3	No	O	NA/TC/TCN	R (15SEP2020)	Y/N
		INFEC	Peritonitis/ Feculant Peritonitis	2	14SEP2020	15/5	3	No	O	NA/TC/TCN	R (18SEP2020)	Y/N
>55/ C459100 1 1011 10111049	3^	INJ&P	Fall/ Fall	2	04OCT2020	27/1	1	No	O	NA	R (04OCT2020)	N/N
			Ligament sprain/ Sprained left ankle	2	04OCT2020	27/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C459100 1 1011 10111050	3^	GENRL	Chills/ Chills	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
			Fatigue/ Fatigue	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ Fever 100.1 F	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1011 10111126	3^	MUSC	Myalgia/ Generalized Muscle aches	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1011 10111138	3^	INJ&P	Chest injury/ Bruised Ribs	1	15SEP2020	15/C	2	No	O	NA	N	N/N
			Hand fracture/ Left Hand Fracture	1	15SEP2020	15/C	2	No	O	NA/TC	N	N/N
			Ligament sprain/ Left Wrist Sprain	1	15SEP2020	15/C	2	No	O	NA/TC	N	N/N
			Ligament sprain/ Sprained left knee	1	15SEP2020	15/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1011 10111145	3^	SKIN	Rash/ Rash on right forearm	1	02SEP2020	1/4	1	No	O	NA	R (05SEP2020)	N/N
>55/ C459100 1 1011 10111152	3^	GASTR	Toothache/ Tooth Pain	1	22SEP2020	21/2	1	No	O	NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1011 10111157	3^	RESP	Nasal congestion/ Nasal Congestion	1	20SEP2020	18/5	1	No	O	NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1011 10111167	3^	GASTR	Diarrhoea/ Diarrhea	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
		INFEC	Conjunctivitis/ Left eye conjunctivitis	1	04SEP2020	2/5	1	No	O	NA/TC	R (08SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1011 10111172	3^	GASTR	Diarrhoea/ Diarrhea	2	29OCT2020	1/C	1	Yes		NA	N	N/N
>55/ C459100 1 1011 10111181	3^	GASTR	Paraesthesia oral/ Tingling around the mouth	1	08OCT2020	1/1	1	Yes		P	R (08OCT2020)	N/N
		NERV	Paraesthesia/ Tingling at finger tips	1	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1012 10121010	3^	GASTR	Nausea/ Nausea	2	26AUG2020	2/1	1	No	O	NA/TC	R (26AUG2020)	N/N
>55/ C459100 1 1012 10121029	3^	MUSC	Muscle spasms/ Cramp in left calf	1	16AUG2020	6/2	1	No	CND	NA	R (17AUG2020)	N/N
>55/ C459100 1 1012 10121033	3^	HEPAT	Hepatic cirrhosis/ Cirrhotic liver	1	22SEP2020	15/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1012 10121039	3^	GENRL	Injection site pain/ Left Arm Injection Site Pain	1	17AUG2020	1/1	1	Yes		NA	R (17AUG2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ HEADACHE	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
		GENRL	Injection site pain/ Arm pain at injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1012 10121045	3^	GENRL	Pyrexia/ Fever	2	11SEP2020	2/2	1	Yes		NA	RS (12SEP2020)	N/N
>55/ C459100 1 1012 10121048	3^	GENRL	Injection site pain/ Left Arm Pain at Injection Site	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/Y
		GENRL	Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Pain/ Body Aches	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ Low Grade Fever	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1012 10121049	3^	GENRL	Pain/ Body Aches	2	12SEP2020	3/4	2	Yes		NA/TC	R (15SEP2020)	N/N
		PSYCH	Nightmare/ Nightmares	2	01OCT2020	22/6	2	No	O	NA	R (06OCT2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	24AUG2020	1/3	2	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1012 10121063		GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	16SEP2020	1/6	1	Yes		NA	R (21SEP2020)	N/N
		MUSC	Arthralgia/ JOINT PAIN	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
			Myalgia/ MUSCLE PAIN	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1012 10121064	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	24AUG2020	1/3	2	Yes		NA	R (26AUG2020)	N/N
		GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Pyrexia/ LOW GRADE FEVER	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Arthralgia/ JOINT PAIN	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
			Myalgia/ MUSCLE PAIN	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1012 10121068	3^	GENRL	Injection site pain/ Left arm muscle pain at injection site	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1012 10121080	3^	GENRL	Fatigue/ FATIGUE	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ FEVER	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
			Injection site swelling/ SWELLING AT INJECTION SITE LEFT ARM	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		GASTR	Nausea/ NAUSEA	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1012 10121086	3^	NERV	Headache/ HEADACHE	2	15SEP2020	1/3	3	Yes		NA	R (17SEP2020)	N/N
		INFEC	Nasopharyngitis/ COMMON COLD	2	26SEP2020	12/4	1	No	O	NA	R (29SEP2020)	N/N
		MUSC	Back pain/ LOWER BACK PAIN	1	30AUG2020	3/4	2	Yes		NA/TC	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1012 10121088	3^	GENRL	Joint stiffness/ Bilateral Knee Stiffness	1	30AUG2020	3/4	1	No	CND	NA	R (02SEP2020)	N/N	
			Musculoskeletal stiffness/ NECK STIFFNESS	1	30AUG2020	3/4	1	Yes		NA	R (02SEP2020)	N/N	
			Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	16SEP2020	1/1	2	Yes		NA	R (16SEP2020)	N/N	
			MUSC	Back pain/ LOW BACK PAIN	2	16SEP2020	1/C	1	Yes		NA	RG	N/N
			Joint stiffness/ Bilateral Knee Stiffness	2	16SEP2020	1/C	1	No	CND	NA	RG	N/N	
			Musculoskeletal stiffness/ NECK STIFFNESS	2	16SEP2020	1/C	1	Yes		NA	RG	N/N	
			MUSC	Musculoskeletal stiffness/ Left Shoulder Stiffness Intermittent	2	23SEP2020	8/C	1	Yes		NA	RG	N/N
			GASTR	Nausea/ Nausea	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
			GENRL	Pain/ Body Aches	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
			NERV	Headache/ Headache	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
EYE	Eye pain/ Bilateral Eye Soreness	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N			
GENRL	Chills/ Chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N			

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C459100 1 1012 10121093	3^	GENRL	Injection site pain/ Left Arm Pain at Injection Site	2	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1012 10121094	3^	GENRL	Fatigue/ FATIGUE	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
			Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1012 10121097	3^	GENRL	Injection site pain/ Left arm localized soreness at injection site	1	02SEP2020	3/2	1	Yes		NA	R (03SEP2020)	N/N
>55/ C459100 1 1012 10121106	3^	GENRL	Injection site pain/ RIGHT ARM INJECTION SITE PAIN	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		EYE	Vision blurred/ Blurred vision	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Arthralgia/ Joint Pain Bilateral Arms	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Arthralgia/ Joint Pain Bilateral Legs	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	23SEP2020	3/1	2	Yes		NA/TC	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ Fatigue	2	23SEP2020	3/2	3	Yes		NA	R (24SEP2020)	N/N
		NERV	Dizziness/ Lightheadedness	2	23SEP2020	3/2	2	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1012 10121109	3^	NEOPL	Infected naevus/ Infection of Mole Lower Right Abdomen	2	14OCT2020	24/C	1	No	CND	NA/TC	RG	N/N
>55/ C459100 1 1012 10121113	3^	NERV	Headache/ HEADACHE	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N
		NERV	Headache/ Headache	2	21SEP2020	1/31	1	Yes		NA	R (21OCT2020)	N/N
>55/ C459100 1 1012 10121114	3^	GENRL	Injection site pain/ INJECTION SITE PAIN LEFT ARM	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Chills/ Chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1012 10121120	3^	GENRL	Injection site pain/ RIGHT ARM INJECTION SITE PAIN	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1012 10121123	3^	INJ&P	Procedural pain/ POST-OP PAIN FROM LEFT ROTATOR CUFF REPAIR	1	18SEP2020	17/C	1	No	CND	NA/TC	RG	N/N
		GENRL	Chills/ BODY CHILLS	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
			Fatigue/ FATIGUE	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ FEVER	2	23SEP2020	1/C	1	Yes		NA/TC	N	N/N
>55/ C459100 1 1012 10121125	3^	MUSC	Back pain/ Mid Back Pain	1	17SEP2020	15/C	1	No	O	NA/TC	RG	N/N
		GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ RIGHT ARM INJECTION SITE PAIN	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
	EYE	Chalazion/ RIGHT CHALAZION	1	10SEP2020	8/C	2	No	O	NA/TC/TCN	RG	N/N	
	INFEC	Hordeolum/ RIGHT STYE	1	10SEP2020	8/C	2	No	O	NA/TC/TCN	RG	N/N	
	INFEC	Sinusitis/ SINUS INFECTION	1	11SEP2020	9/12	2	No	O	NA/TC	R (22SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INFEC	Cellulitis orbital/ RIGHT EYE CELLULITIS	1	12SEP2020	10/5	2	No	O	NA/TC	RS (16SEP2020)	N/N
>55/ C459100 1 1012 10121126	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 1 1012 10121127	3^	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/4	1	Yes		NA	R (07SEP2020)	N/N
		MUSC	Pain in extremity/ LEFT ARM PAIN	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Injection site pain/ Left Arm Injection Site Pain	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1012 10121128	3^	GENRL	Fatigue/ Fatigue	1	05SEP2020	3/3	1	Yes		NA	R (07SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N
			Injection site pain/ Right Arm Injection Site Pain	2	25SEP2020	2/11	1	Yes		NA	R (05OCT2020)	N/N
>55/ C459100 1 1012 10121135	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	04SEP2020	1/5	2	Yes		NA	R (08SEP2020)	N/N
		GENRL	Injection site pain/ Left Arm Pain at Injection Site	2	25SEP2020	1/6	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ Chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ Headache	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C459100 1 1012 10121139	3^	SKIN	Urticaria/ Hives Bilateral Legs	1	20SEP2020	16/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1012 10121160	3^	GENRL	Chills/ Chills	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
			Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Myalgia/ Muscle Pains	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1012 10121165	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ FATIGUE	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
			Pain/ BODY ACHES	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1012 10121168	3^	MUSC	Arthralgia/ LEFT WRIST INSIDE PAIN	1	10SEP2020	1/1	1	No	CND	NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	12SEP2020	3/1	1	Yes		NA	R (12SEP2020)	N/N
		NERV	Dysgeusia/ METALLIC TASTE IN MOUTH	1	12SEP2020	3/1	1	Yes		NA	R (12SEP2020)	N/N
		GASTR	Diarrhoea/ DIARRHEAL EPISODE	2	03OCT2020	4/1	2	No	CND	NA	R (03OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	03OCT2020	4/1	3	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100 1 1012 10121186	3^	GENRL	Injection site pain/ Pain at Injection Site	1	21SEP2020	1/5	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Chills/ Chills	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
			Fatigue/ Fatigue	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
			Pain/ Body Aches	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C459100 1 1013 10131130	3^	NERV	Headache/ Frontal headache	2	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11013 10131133	3^	MUSC	Neck pain/ CERVICAL PAIN	2	09SEP2020	9/C	3	No	O	NA/TC	RG	N/N
>55/ C459100 11013 10131176	3^	BLOOD	Leukopenia/ LEUKOPENIA	1	29AUG2020	17/10	2	No	O	NA/TCN	R (07SEP2020)	N/N
		GASTR	Abdominal adhesions/ abdominal adhesions	1	29AUG2020	17/2	3	No	O	NA/TC	R (30AUG2020)	Y/N
			Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	1	29AUG2020	17/2	2	No	O	NA/TCN	R (30AUG2020)	Y/N
		INFEC	Sepsis/ sepsis	1	29AUG2020	17/19	3	No	O	NA	R (16SEP2020)	N/N
		METAB	Hyponatraemia/ HYPONATREMIA	1	29AUG2020	17/10	2	No	O	NA/TC	R (07SEP2020)	N/N
		PSYCH	Mental status changes/ altered mental status	1	29AUG2020	17/19	3	No	CND	NA	R (16SEP2020)	N/N
		RENAL	Acute kidney injury/ acute renal failure	1	29AUG2020	17/19	3	No	O	NA	R (16SEP2020)	N/N
		BLOOD	Anaemia/ anemia	1	30AUG2020	18/18	3	No	O	NA	R (16SEP2020)	N/N
		CARD	Cardiac failure congestive/ CONGESTIVE HEART FAILURE	1	30AUG2020	18/18	3	No	O	NA	R (16SEP2020)	N/N
		METAB	Hypokalaemia/ hypokalemia	1	30AUG2020	18/18	3	No	O	NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Acute respiratory failure/ acute hypoxic respiratory failure	1	30AUG2020	18/13	3	No	O	NA	R (11SEP2020)	Y/N
			Pneumonia aspiration/ ASPIRATION PNEUMONIA	1	30AUG2020	18/18	2	No	O	NA/TCN	R (16SEP2020)	Y/N
		CARD	Left ventricular hypertrophy/ MILD CONCENTRIC LEFT VENTRICULAR HYPERTROPHY	1	16SEP2020	35/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1013 10131186	3^	INFEC	Infected bite/ 2ND TOE OF RIGHT FOOT BUG BITE INFECTION	1	02SEP2020	21/19	2	No	O	NA/TC	R (20SEP2020)	N/N
		INJ&P	Meniscus injury/ TORN MENISCUS RIGHT KNEE	1	02SEP2020	21/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1013 10131236	3^	GENRL	Pain/ BODY ACHES	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1013 10131244	3^	PSYCH	Restlessness/ RESTLESSNESS	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1013 10131248			Pyrexia/ LOW GRADE FEVER	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
>55/ C459100 1 1013 10131260	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1013 10131265	3^	GENRL	Fatigue/ FATIGUE	1	21AUG2020	2/5	1	Yes		NA	R (25AUG2020)	N/N
>55/ C459100 1 1013 10131277	3^	GENRL	Chills/ CHILLS	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Fatigue/ FATIGUE	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1013 10131278	3^	GENRL	Fatigue/ FATIGUE	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1013 10131279	3^	GENRL	Chills/ CHILLS	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		MUSC	Musculoskeletal stiffness/ STIFF NECK	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ HEADACHE	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	21SEP2020	8/2	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1013 10131297	3^	GENRL	Fatigue/ FATIGUE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1013 10131310	3^	NERV	Headache/ HEADACHE	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Pain/ BODY ACHES	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1013 10131320	3^	NERV	Dizziness/ LIGHTHEADEDNESS	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		RESP	Dyspnoea/ SHORTNESS OF BREATH	2	16SEP2020	2/2	1	No	O	NA	R (17SEP2020)	N/N
>55/ C459100 1 1013 10131324	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	7/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1013 10131326	3^	MUSC	Arthralgia/ JOINT ACHES	1	07SEP2020	13/37	1	No	O	NA	R (13OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GASTR	Diarrhoea/ DIARRHEA	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C459100 1 1013 10131331	3^	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	03NOV2020	49/8	1	No	O	NA/TC	R (10NOV2020)	N/N
>55/ C459100 1 1013 10131333	3^	INJ&P	Radius fracture/ FRACTURE RIGHT DISTAL RADIUS	2	28SEP2020	13/8	2	No	O	NA/TC	R (05OCT2020)	N/N
			Ulna fracture/ FRACTURE RIGHT DISTAL ULNA	2	28SEP2020	13/8	2	No	O	NA/TC	R (05OCT2020)	N/N
		SURG	Open reduction of fracture/ OPEN REDUCTION INTERNAL FIXATION RIGHT RADIUS	2	05OCT2020	20/1	2	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C459100 1 1013 10131341	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	3/3	2	Yes		NA/TC	R (21SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	19SEP2020	3/3	2	Yes		NA/TC	R (21SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	02SEP2020	7/2	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1013 10131346	3^	GENRL	Pain/ BODY ACHES	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
1 1013 10131347		SKIN	Night sweats/ NIGHT SWEATS	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1013 10131347	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	28AUG2020	2/3	2	Yes		NA/TC	R (30AUG2020)	N/N
1 1013 10131350		GENRL	Pyrexia/ LOW GRADE FEVER	2	19SEP2020	3/1	2	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C459100 1 1013 10131356	3^	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ FRONTAL HEADACHE	2	23SEP2020	2/4	2	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1013 10131358	3^	INJ&P	Fall/ Fall	1	07SEP2020	8/1	2	No	O	NA/TC	R (07SEP2020)	N/N
>55/ C459100	3^	MUSC	Arthralgia/ LEFT SHOULDER SORENESS	2	05OCT2020	15/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1013 10131359 >55/ C459100 1 1013 10131360	3^	GENRL	Fatigue/ FATIGUE	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1013 10131368	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1013 10131372	3^	RESP	Nasal congestion/ NASAL CONGESTION	2	26SEP2020	4/C	1	Yes		NA	RG	N/N
			Oropharyngeal pain/ SORE THROAT	2	26SEP2020	4/3	1	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C459100 1 1013 10131384	3^	GENRL	Chills/ CHILLS	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	2	22SEP2020	2/4	2	Yes		NA/TC	R (25SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	24SEP2020	4/1	2	Yes		NA/TC	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1013 10131402	3^	GENRL	Chills/ CHILLS	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1013 10131415	3^	GENRL	Chills/ CHILLS	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
		GASTR	Nausea/ NAUSEA	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ FEVER	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C459100 1 1013 10131428	3^	MUSC	Musculoskeletal discomfort/ RIGHT SHOULDER DISCOMFORT	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1013 10131431	3^	MUSC	Musculoskeletal stiffness/ BODY MUSCLE STIFFNESS	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1013 10131434	3^	GENRL	Chills/ CHILLS	2	25SEP2020	2/2	2	Yes		NA/TC	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Fatigue/ FATIGUE	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1013 10131457	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 1 1013 10131460	3^	GENRL	Pain/ BODY ACHES	1	08SEP2020	1/2	2	Yes		NA/TC	R (09SEP2020)	N/N
			Pyrexia/ LOW GRADE FEVER	1	08SEP2020	1/2	2	Yes		NA/TC	R (09SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1013 10131461	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	30SEP2020	1/7	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1013 10131462	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1013 10131466	3^	GENRL	Fatigue/ FATIGUE	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
		INV	Body temperature increased/ ELEVATED TEMPERATURE	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		MUSC	Pain in extremity/ LEFT ARM PAIN	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Pyrexia/ LOW GRADE FEVER	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		NERV	Headache/ HEADACHE LEFT SIDE	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1013 10131482	3^	MUSC	Myalgia/ MUSCLE PAIN	1	11SEP2020	3/4	1	Yes		NA	R (14SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	11SEP2020	3/8	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1013 10131488	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	02OCT2020	2/4	1	Yes		NA	R (05OCT2020)	N/N
			Pain/ BODY ACHES	2	02OCT2020	2/4	1	Yes		NA	R (05OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	02OCT2020	2/4	1	Yes		NA	R (05OCT2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1013 10131489		NERV	Headache/ HEADACHE	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
		NERV	Headache/ TEMPORAL HEADACHE	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1013 10131494	3^	GASTR	Nausea/ NAUSEA	2	02OCT2020	2/C	2	Yes		NA	RG	N/N
		GENRL	Pain/ BODY ACHES	2	03OCT2020	3/C	2	Yes		NA/TC	RG	N/N
>55/ C459100 1 1013 10131496	3^	GENRL	Pain/ BODY ACHES	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1013 10131505	3^	GENRL	Pyrexia/ Low grade fever	1	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
		GENRL	Pain/ BODY ACHES	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N
		NERV	Headache/ FRONTAL HEADACHE	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1013 10131506	3^	GENRL	Pain/ BODY ACHES	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	04OCT2020	4/1	1	Yes		NA/TC	R (04OCT2020)	N/N
>55/ C459100 1 1013 10131511	3^	GENRL	Fatigue/ FATIGUE	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1013 10131517	3^	GENRL	Injection site pain/ INJECTION SITE PAIN TO LEFT ARM*		10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
			GENRL	Fatigue/ FATIGUE	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)
		CARD	Myocardial infarction/ MYOCARDIAL INFARCTION	2	08NOV2020	40/3	3	No	O	NA	R (10NOV2020)	Y/N
>55/ C459100 1 1013 10131525	3^	GENRL	Fatigue/ FATIGUE	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1013 10131536	3^	GASTR	Dry mouth/ DRY MOUTH	1	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C459100 1 1013 10131539	3^	SKIN	Rash/ RASH NECK	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	17SEP2020	3/1	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	08OCT2020	3/1	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1013 10131548	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1013 10131554		GENRL	Injection site pain/ INJECTION PAIN	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
			Pain/ BODY PAIN	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C459100 1 1013 10131558	3^	GASTR	Nausea/ NAUSEA	2	07OCT2020	2/C	1	Yes		NA	RG	N/N
		GENRL	Chills/ CHILLS	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
			Pain/ BODY ACHES	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
			Pyrexia/ LOW GRADE FEVER	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		NERV	Dizziness/ DIZZINESS	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	14OCT2020	9/C	1	Yes		NA	RG	N/N
>55/ C459100 1 1013 10131560	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1013 10131561	3^	NERV	Headache/ HEADACHE	2	08OCT2020	2/1	2	Yes		NA	R (08OCT2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	09OCT2020	3/3	1	Yes		NA	R (11OCT2020)	N/N
		NERV	Headache/ Headache	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1013 10131574	3^	VASC	Hot flush/ Hot flushes	1	17SEP2020	2/5	1	Yes		NA	R (21SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	24SEP2020	8/2	2	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C459100 1 1013 10131578	3^	GENRL	Pain/ BODY ACHES	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Pyrexia/ LOW GRADE FEVER	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	24SEP2020	8/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1013 10131583	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	08OCT2020	1/2	1	Yes		NA/TCN	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1013 10131590	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C459100 1 1013 10131602	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 1013 10131604	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1013 10131609	3^	GENRL	Fatigue/ fatigue	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1013 10131618	3^	GASTR	Nausea/ NAUSEA	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
			Fatigue/ FATIGUE	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ HEADACHE	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N
>55/ C459100 1 1013 10131620	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	10OCT2020	17/7	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 1013 10131640	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		NERV	Headache/ HEADACHE	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1015 10151003	3^	GENRL	Fatigue/ Fatigue	2	01SEP2020	1/6	1	Yes		NA/TC	R (06SEP2020)	N/N
			Injection site erythema/ Redness at injection site	2	01SEP2020	1/6	1	Yes		NA/TC	R (06SEP2020)	N/N
			Injection site pain/ Soreness at injection site	2	01SEP2020	1/6	1	Yes		NA/TC	R (06SEP2020)	N/N
			Pyrexia/ Low grade fever - 98.9	2	01SEP2020	1/6	1	Yes		NA/TC	R (06SEP2020)	N/N
>55/ C459100 1 1015 10151019	3^	MUSC	Arthralgia/ Joint pain in left arm	2	03SEP2020	2/C	1	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1015 10151057	3^	GENRL	Injection site pain/ Pain at injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Malaise/ General Malaise	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Headache	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1015 10151065	3^	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/5	1	Yes		NA/TC	R (13SEP2020)	N/N
>55/ C459100 1 1015 10151096	3^	GENRL	Vaccination site pain/ Whole arm pain throughout - arm where IP vaccine was received	2	14SEP2020	1/4	1	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Malaise/ Malaise	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1015 10151111	3^	EAR	Ear pruritus/ Itching of ears	1	08SEP2020	15/2	1	No	O	NA	R (09SEP2020)	N/N
		RESP	Throat irritation/ Itching of throat	1	08SEP2020	15/2	1	No	O	NA	R (09SEP2020)	N/N
>55/ C459100 1 1015 10151127	3^	GENRL	Injection site pain/ Injection site soreness	2	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		EAR	Ear pain/ Ear pain	2	29OCT2020	42/2	1	No	O	NA/TC	R (30OCT2020)	N/N
>55/ C459100 1 1015 10151129	3^	MUSC	Joint stiffness/ Bilateral knee stiffness	2	23SEP2020	7/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1015 10151142	3^	GENRL	Injection site swelling/ 5cm swelling at injection site	1	28AUG2020	1/3	1	Yes		NA/TC	R (30AUG2020)	N/N
		MUSC	Myalgia/ Myalgia	1	28AUG2020	1/3	1	Yes		NA/TC	R (30AUG2020)	N/N
		GENRL	Influenza like illness/ Flu-like symptom - fatigue	2	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
>55/ C459100 1 1015 10151144	3^	GENRL	Injection site pain/ Pain at injection site	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/Y
>55/ C459100 1 1015 10151156	3^	GENRL	Malaise/ Malaise	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1015 10151158	3^	MUSC	Back pain/ Left lower back pain	2	24SEP2020	2/7	2	No	O	NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1015 10151168	3^	GENRL	Musculoskeletal pain/ Upper left gluteal pain	2	24SEP2020	2/7	2	No	O	NA	R (30SEP2020)	N/N
			Fatigue/ Fatigue	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	02SEP2020	1/2	2	Yes		NA	R (03SEP2020)	N/N
			Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1015 10151169	3^	GENRL	Pyrexia/ Fever - 101.0	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1015 10151173	3^	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/Y
GENRL		Injection site pain/ Injection site soreness	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N	
>55/ C459100 1 1015 10151178	3^	GENRL	Injection site pain/ Injection site soreness	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
		MUSC	Pain in extremity/ Left leg pain from hip to ankle	2	21OCT2020	28/2	2	No	O	NA/TC	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1015 10151181	3^	MUSC	Arthralgia/ Joint pain (hands, elbows, knees, and hips)	1	05SEP2020	2/5	1	Yes		NA/TC	R (09SEP2020)	N/N
		MUSC	Arthralgia/ Joint pain (hips, fingers, elbows)	1	19SEP2020	16/3	1	Yes		NA	R (21SEP2020)	N/N
>55/ C459100 1 1015 10151186	3^	GASTR	Nausea/ Nausea	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N
		GENRL	Chills/ Chills	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N
			Pyrexia/ Fever 100.4	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain in left arm	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	30SEP2020	3/1	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1015 10151190	3^	GENRL	Injection site pain/ Soreness at injection site	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N
>55/ C459100 1 1015 10151195	3^	GENRL	Chills/ Chills	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Fatigue	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1015 10151216	3^	MUSC	Myalgia/ Muscle aches	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Malaise/ Malaise	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1015 10151237	3^	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		RESP	Rhinorrhoea/ Nasal discharge	1	26SEP2020	16/2	1	No	O	NA	R (27SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness - localized achiness	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		MUSC	Arthralgia/ worsening of right knee pain	1	07AUG2020	8/C	2	No	O	NA/TC/TCN	N	N/N
>55/ C459100 1 1016 10161022	3^	SKIN	Dermatitis contact/ diffuse contact dermatitis	1	23AUG2020	21/8	1	No	O	NA/TC	R (30AUG2020)	N/N
>55/ C459100	3^	INFEC	Parotitis/ Parotitis	1	20SEP2020	49/12	1	No	O	NA/TC	RS (01OCT2020)	N/N
		GASTR	Gastroesophageal reflux disease/	2	09SEP2020	17/C	2	No	O	NA/TC/TCN	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1016 10161035			Worsening of of Gastroesophageal Reflux Disease									
>55/ C459100 1 1016 10161059	3^	INFEC	Sinusitis/ Sinusitis	1	10AUG2020	6/6	1	No	O	NA/TC	R (15AUG2020)	N/N
>55/ C459100 1 1016 10161063	3^	GENRL	Fatigue/ fatigue	2	03SEP2020	9/1	2	Yes		NA	R (03SEP2020)	N/N
>55/ C459100 1 1016 10161131	3^	GENRL	Injection site pain/ injection site pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		MUSC	Arthralgia/ joint pain	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
			Myalgia/ muscle pain	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1016 10161141	3^	MUSC	Myalgia/ muscle pain	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C459100 1 1016 10161142	3^	MUSC	Myalgia/ muscle pain	2	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1016 10161151	3^	INJ&P	Muscle strain/ strained thigh muscle	2	11SEP2020	2/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1016 10161162	3^	INJ&P	Concussion/ Concussion	1	08SEP2020	19/8	1	No	O	NA/TC	R (15SEP2020)	N/N
			Fall/ Fall While Hiking	1	08SEP2020	19/1	1	No	O	NA	R (08SEP2020)	N/N
			Skin abrasion/ Abrasions to Head	1	08SEP2020	19/8	1	No	O	NA/TC	R (15SEP2020)	N/N
>55/ C459100 1 1016 10161165	3^	INFEC	Gastroenteritis/ Gastroenteritis	1	25AUG2020	5/2	1	No	O	NA	R (26AUG2020)	N/N
		RENAL	Obstructive nephropathy/ right kidney obstruction	2	28SEP2020	18/11	2	No	O	NA	R (08OCT2020)	N/N
			Urinary tract obstruction/ left kidney obstruction	2	28SEP2020	18/5	2	No	O	NA	R (02OCT2020)	N/N
>55/ C459100 1 1016 10161174	3^	MUSC	Costochondritis/ Costochondritis	1	02SEP2020	10/5	1	No	O	NA	R (06SEP2020)	N/N
>55/ C459100 1 1016 10161197	3^	GENRL	Oedema peripheral/ Pedal Edema	1	03SEP2020	8/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1016 10161203	3^	GENRL	Chills/ chills	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ injection site pain	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ headache	2	18SEP2020	1/2	2	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C459100 1 1016 10161247	3^	MUSC	Pain in extremity/ leg aches	1	09SEP2020	6/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1016 10161257	3^	INJ&P	Fall/ Fall, down stair	1	13SEP2020	6/1	2	No	O	NA	R (13SEP2020)	N/N
			Fibula fracture/ Left Fibula Fracture	1	13SEP2020	6/C	2	No	O	NA/TC	N	N/N
			Patella fracture/ Left Patella Fracture	1	13SEP2020	6/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1016 10161271	3^	GASTR	Nausea/ nausea	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
		GENRL	Chills/ chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		MUSC	Myalgia/ muscle aches	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1016 10161274	3^	SKIN	Hyperhidrosis/ excessive sweating	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 1 1016 10161274	3^	PSYCH	Suicidal ideation/ fleeting suicidal ideation	2	03OCT2020	3/1	1	No	O	NA	R (03OCT2020)	N/N
>55/ C459100 1 1016 10161282	3^	METAB	Gout/ Gout Right Foot, First Digit	1	26SEP2020	16/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1018 10181002	2^	GENRL	Fatigue/ Fatigue	2	20AUG2020	2/2	1	No	O	NA	R (21AUG2020)	N/N
>55/ C459100 1 1018 10181005	2^	GENRL	Injection site pain/ Injection site pain	2	20AUG2020	2/2	1	Yes		NA/TC	R (21AUG2020)	N/N
>55/ C459100 1 1018 10181073	3^	NERV	Headache/ Headache	2	23SEP2020	29/1	1	No	O	NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1018 10181075	3^	GENRL	Fatigue/ Fatigue	2	01SEP2020	6/2	1	Yes		NA	R (02SEP2020)	N/N
>55/ C459100 1 1018 10181110	3^	RENAL	Urinary retention/ Urinary Retention (AE of Botox Injection)	2	16SEP2020	17/C	1	No	CD	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1018 10181112	3^	INJ&P	Meniscus injury/ Right Knee Medial Meniscus Tear	2	01SEP2020	2/C	2	No	O	NA/TCN	RG	N/N
>55/ C459100 1 1018 10181123	3^	MUSC	Back pain/ Acute Back Pain (musculoskeletal)	2	23SEP2020	23/C	2	No	O	NA	RG	N/N
>55/ C459100 1 1018 10181132	3^	INV	Cardiac stress test abnormal/ CARDIAC STRESS TEST ABNORMAL, HOSPITALIZED	2	08SEP2020	8/C	3	No	O	NA	N	Y/N
>55/ C459100 1 1018 10181175	3^	GENRL	Injection site pain/ Pain at the Injection Side	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1018 10181190	3^	GENRL	Injection site pain/ Soreness at injection site	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/Y
>55/ C459100 1 1018 10181248	3^	SKIN	Actinic keratosis/ Actinic Keratosis flare up	1	08SEP2020	8/1	2	No	O	NA/TC/TCN	R (08SEP2020)	N/N
>55/ C459100 1 1018 10181265	3^	NERV	Headache/ headache	1	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N
		NERV	Headache/ headache	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1018 10181270	3^	GENRL	Injection site pain/ injection site pain	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
>55/ C459100 1 1018 10181274	3^	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
			Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ Injection site tenderness	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1018 10181296	3^	GENRL	Pain/ Body aches and pain	1	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		RESP	Upper-airway cough syndrome/ post-nasal drip	1	01OCT2020	16/6	1	No	O	NA	R (06OCT2020)	N/N
		GENRL	Pyrexia/ Fever	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C459100 1 1018 10181308	3^	GASTR	Diarrhoea/ Diarrhea	1	26SEP2020	3/6	1	Yes		NA/TC	R (01OCT2020)	N/N
		GENRL	Injection site pain/ Injection site arm pain	1	26SEP2020	3/1	1	Yes		NA	R (26SEP2020)	N/N
			Pyrexia/ Fever, low grade	1	26SEP2020	3/2	1	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	1	26SEP2020	3/3	2	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C459100 1 1019 10191001	3^	GENRL	Injection site pain/ Mild Injection Site Pain	1	11AUG2020	2/2	1	Yes		NA	R (12AUG2020)	N/N
		GENRL	Injection site swelling/ Mild Swelling at Injection Site	1	12AUG2020	3/1	1	Yes		NA	R (12AUG2020)	N/N
		GENRL	Injection site erythema/ Mild Redness at Injection Site	2	03SEP2020	3/1	1	Yes		NA	R (03SEP2020)	N/N
			Injection site pain/ Mild Injection Pain	2	03SEP2020	3/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 1 1019 10191010	3^	GASTR	Diarrhoea/ Diarrhea	1	17AUG2020	7/11	2	No	O	NA	R (27AUG2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	27AUG2020	17/3	4	No	O	NA	R (29AUG2020)	Y/N
		PSYCH	Mental status changes/ Mental State Status Change	2	02OCT2020	32/1	2	No	O	NA	R (02OCT2020)	N/N
>55/ C459100 1 1019 10191025	3^	GENRL	Injection site erythema/ Redness Mild Injection Site	1	13AUG2020	1/1	1	Yes		NA	R (13AUG2020)	N/N
			Injection site pain/ injection pain mild	1	13AUG2020	1/1	1	Yes		NA	R (13AUG2020)	N/N
			Injection site swelling/ Swelling mild at site Injection	1	13AUG2020	1/1	1	Yes		NA	R (13AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1019 10191035	3^	GENRL	Fatigue/ fatigue mild	1	14AUG2020	2/1	1	Yes		NA	R (14AUG2020)	N/N
		NERV	Dizziness postural/ orthostatic dizziness	1	20AUG2020	8/1	1	Yes		NA	R (20AUG2020)	N/N
		GENRL	Fatigue/ Mild Fatigue	1	14AUG2020	2/1	1	Yes		NA	R (14AUG2020)	N/N
			Injection site erythema/ Mild Redness at Injection Site	1	14AUG2020	2/5	1	Yes		NA	R (18AUG2020)	N/N
			Injection site pain/ Mild Injection Site Pain	1	14AUG2020	2/2	1	Yes		NA	R (15AUG2020)	N/N
			Injection site swelling/ Mild Swelling at Injection Site	1	14AUG2020	2/3	1	Yes		NA	R (16AUG2020)	N/N
		MUSC	Myalgia/ Mild Muscle Pain	1	14AUG2020	2/1	1	Yes		NA	R (14AUG2020)	N/N
		GENRL	Injection site erythema/ Mild Redness at Injection Site	2	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N
			Injection site pain/ Mild Injection Site Pain	2	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
			Injection site swelling/ Mild Swelling at Injection Site	2	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ Mild Chills	2	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
			Fatigue/ Moderate Fatigue	2	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1019 10191037	3 [^]	SURG	Injection site erythema/ Moderate Redness at Injection Site	2	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
			MUSC	Myalgia/ Mild Muscle Pain	2	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
			NERV	Headache/ Mild Headache	2	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
			GENRL	Fatigue/ Mild Fatigue	2	04SEP2020	3/1	1	Yes		NA	R (04SEP2020)	N/N
			MUSC	Arthralgia/ Mild Joint Pain	2	04SEP2020	3/1	1	Yes		NA	R (04SEP2020)	N/N
			GENRL	Injection site erythema/ Mild Redness at Injection Site	2	05SEP2020	4/2	1	Yes		NA	R (06SEP2020)	N/N
>55/ C459100 1 1019 10191118	3 [^]	GASTR	Cardioversion/ Defibrillator Discharge	2	15OCT2020	42/1	2	No	O	NA	R (15OCT2020)	N/N	
			GENRL	Asthenia/ Weakness	2	27OCT2020	54/C	2	No	O	NA	UNK	Y/N
>55/ C459100 1 1019 10191146	3 [^]	GASTR	Haemorrhoids/ Worsening of Hemorrhoids	1	10SEP2020	15/27	1	Yes		NA	R (06OCT2020)	N/N	
			MUSC	Osteoarthritis/ Worsening of Osteoarthritis	1	10SEP2020	15/C	1	Yes		NA	N	N/N
>55/ C459100 1 1019 10191146	3 [^]	NEOPL	Hepatic cancer metastatic/ poorly differentiated carcinoma metastatic to liver, unknown primary	2	27OCT2020	36/C	3	No	O	NA	N	Y/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1019 10191150	3^	GENRL	Injection site pain/ Muscle Pain Injection Site	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1019 10191169	3^	INJ&P	Ligament sprain/ Sprained Wrist Right	1	22SEP2020	15/7	1	No	O	NA	R (28SEP2020)	N/N
>55/ C459100 1 1019 10191229	3^	INJ&P	Road traffic accident/ Motor Vehicle Collision	2	05NOV2020	22/C	4	No	O	NA	UNK	Y/N
>55/ C459100 1 1019 10191241	3^	GENRL	Chills/ Mild Chills	1	30SEP2020	3/3	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Mild Fatigue	1	30SEP2020	3/3	1	Yes		NA	R (02OCT2020)	N/N
			Pain/ Moderate Body Aches	1	30SEP2020	3/3	2	Yes		NA	R (02OCT2020)	N/N
		GENRL	Injection site swelling/ Injection site swelling	2	20OCT2020	2/4	1	Yes		NA	R (23OCT2020)	N/N
>55/ C459100 1 1021 10211001	3^	GASTR	Diarrhoea/ Diarrhea	1	11AUG2020	2/4	1	Yes		NA	R (14AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	1	11AUG2020	2/4	1	Yes		NA	R (14AUG2020)	N/N
		RESP	Rhinorrhoea/ Runny nose	1	11AUG2020	2/4	1	Yes		NA	R (14AUG2020)	N/N
>55/ C459100 1 1021 10211024	3^	GASTR	Rectal haemorrhage/ Rectal Bleeding	1	18AUG2020	7/C	1	No	O	NA	N	N/N
>55/ C459100 1 1021 10211030	3^	RENAL	Dysuria/ Painful Urination	1	16AUG2020	4/4	1	No	O	NA	R (19AUG2020)	N/N
>55/ C459100 1 1021 10211057	3^	NEOPL	Basal cell carcinoma/ Basal cell skin cancer (head)	1	10SEP2020	23/C	2	No	O	NA	N	N/N
>55/ C459100 1 1021 10211063	3^	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ Fever	2	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1021 10211068	3^	GENRL	Injection site mass/ Bump under skin near injection site Left arm	2	09SEP2020	2/19	1	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1021 10211078	3^	GENRL	Chills/ Body Chills	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
			Fatigue/ Fatigue	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
			Pain/ Body Aches	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
			Pyrexia/ Fever	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
>55/ C459100 1 1021 10211081	3^	INJ&P	Ligament sprain/ L Knee Sprain	2	14OCT2020	30/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1021 10211084	3^	INJ&P	Ligament sprain/ R Knee Sprain	1	03SEP2020	11/4	1	No	O	NA/TC	R (06SEP2020)	N/N
>55/ C459100 1 1021 10211093	3^	GENRL	Fatigue/ Fatigue	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/Y
>55/ C459100 1 1021 10211095	3^	MUSC	Plantar fasciitis/ Plantar Fasciitis (right foot)	1	28AUG2020	4/C	1	No	O	NA	N	N/N
		GENRL	Fatigue/ Fatigue	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ Fever (100.6)	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1021 10211100	3^	GENRL	Injection site pain/ Intermittent Soreness at Injection Site	1	26AUG2020	1/C	2	Yes		NA	RG	N/Y
>55/ C459100 1 1021 10211113	3^	GENRL	Injection site pain/ Soreness in left arm at injection site	1	28AUG2020	1/C	2	Yes		NA	RG	N/N
>55/ C459100 1 1021 10211121	3^	RENAL	Pollakiuria/ Increased Frequency of Urination	2	28SEP2020	8/C	1	No	O	NA	N	N/N
>55/ C459100 1 1021 10211128	3^	INJ&P	Ligament sprain/ L Ankle Sprain	2	02OCT2020	11/C	2	No	O	NA	RG	N/N
			Skin laceration/ Forehead Laceration	2	02OCT2020	11/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1021 10211129	3^	METAB	Hypoglycaemia/ Hypoglycemia	2	14OCT2020	24/1	3	No	O	NA	R (14OCT2020)	N/N
>55/ C459100 1 1021 10211131	3^	INFEC	Bacterial infection/ Bacterial Infection right hand	1	21SEP2020	21/12	2	No	O	NA/TC	R (02OCT2020)	N/N
>55/ C459100	3^	GENRL	Peripheral swelling/ Swelling in right leg	1	02SEP2020	2/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1021 10211134 >55/ C459100	3^	GENRL	Pyrexia/ fever	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
1 1021 10211139 >55/ C459100	3^	MUSC	Tendonitis/ Right Inflamed Achilles Tendon	1	15SEP2020	14/C	2	No	O	NA/TC/TCN	N	N/N
1 1021 10211144 >55/ C459100	3^	GENRL	Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
1 1021 10211161 >55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
1 1021 10211162 >55/ C459100	3^	GENRL	Pyrexia/ fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
1 1021 10211166 >55/ C459100	3^	MUSC	Myalgia/ Left arm muscle soreness	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
1 1021 10211166 >55/ C459100	3^	MUSC	Pain in extremity/ Left Arm Soreness	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
1 1021 10211166 >55/ C459100	3^	RESP	Nasal congestion/ Nasal congestion	1	10SEP2020	2/15	2	No	O	NA/TC	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1021 10211172 >55/ C459100 1 1021 10211178	3^	GENRL	Fatigue/ fatigue	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
			Injection site pain/ injection site soreness left arm	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
			Fatigue/ fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
>55/ C459100 1 1021 10211183	3^	GENRL	Fatigue/ fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1021 10211188	3^	GENRL	Chills/ Chills	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1021 10211189	3^	SKIN	Alopecia/ Hair Loss	1	18SEP2020	9/C	2	No	O	NA/TC	RG	N/N
>55/ C459100	3^	NERV	Cerebrovascular accident/ Stroke (CVA)	2	02NOV2020	33/C	3	No	O	NA	RG	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1021 10211190 >55/ C459100	3^	GENRL	Injection site rash/ Rash at Injection Site	2	04OCT2020	4/2	2	Yes		NA/TC	R (05OCT2020)	N/N
1 1021 10211201 >55/ C459100	3^	MUSC	Arthralgia/ Joint pain (bilateral shoulders, knees, hips)	1	22SEP2020	5/3	1	No	O	NA/TC	R (24SEP2020)	N/N
1 1021 10211234 >55/ C459100	3^	NERV	Headache/ Intermittent Headaches	1	20SEP2020	3/4	1	Yes		NA	R (23SEP2020)	N/N
1 1021 10211238 >55/ C459100	3^	GENRL	Injection site pain/ Mild Injection Site Pain	1	17AUG2020	1/1	1	Yes		NA	R (17AUG2020)	N/N
1 1022 10221011 >55/ C459100	3^	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/2	2	Yes		NA	R (19AUG2020)	N/N
1 1022 10221012 >55/ C459100	3^	GENRL	Injection site pain/ Moderate Injection Site Pain	1	17AUG2020	1/2	2	Yes		NA	R (18AUG2020)	N/N
1 1022 10221014		GENRL	Injection site pain/ Injection Site Pain	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Generalized Myalgias	2	08SEP2020	1/1	2	Yes		NA	R (08SEP2020)	N/N
>55/ C459100 1 1022 10221021	3^	GENRL	Injection site pain/ Mild Injection Site Pain	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
		GENRL	Injection site pain/ Mild Injection site pain	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 1 1022 10221022	3^	GENRL	Pyrexia/ Fever	2	14SEP2020	7/1	1	Yes		NA	R (14SEP2020)	N/N
>55/ C459100 1 1022 10221026	3^	GENRL	Chills/ Chills	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Injection site pain/ Pain at the injection site	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ Fever	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1022 10221032	3^	GASTR	Diarrhoea/ Loose Stools	1	02SEP2020	14/1	1	No	O	NA	R (02SEP2020)	N/N
			Nausea/ Nausea	1	02SEP2020	14/1	1	No	O	NA	R (02SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1022 10221034	3^	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/3	2	Yes		NA	R (22AUG2020)	N/N
		MUSC	Myalgia/ Generalized Myalgias	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	14SEP2020	26/3	1	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ Moderate Injection site pain	1	14SEP2020	26/7	2	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1022 10221041	3^	GENRL	Injection site pain/ Injection Site Pain	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Chills/ Chills	2	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ Fever	2	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1022 10221042	3^	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
			Pyrexia/ Low Grade Fever	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		NERV	Headache/ Headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1022 10221044	3^	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
>55/ C459100 1 1022 10221050	3^	GENRL	Injection site pain/ Mild Injection Site Pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/Y
			Injection site pain/ Mild Injection Site Pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/Y
>55/ C459100 1 1022 10221056	3^	GENRL	Injection site pain/ Mild Injection site pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1022 10221060	3^	GASTR	Diarrhoea/ Diarrhea	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
		GENRL	Chills/ Chills	2	14SEP2020	1/1	2	Yes		NA	R (14SEP2020)	N/N
			Injection site pain/ Injection site pain	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
			Pyrexia/ Fever	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		MUSC	Myalgia/ Generalized Myalgias	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N
>55/ C459100 1 1022 10221063	3^	GENRL	Injection site pain/ Mild Injection site pain*		25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
>55/ C459100 1 1022 10221065	3^	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	2/C	2	Yes		NA	N	N/N
		MUSC	Myalgia/ Generalized Myalgias	2	17SEP2020	2/C	2	Yes		NA	N	N/N
		NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1022 10221068	3^	GENRL	Injection site pain/ Mild Injection Site Pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1022 10221071	3^	GENRL	Injection site pain/ Mild Injection site pain	1	27AUG2020	2/6	1	Yes		NA	R (01SEP2020)	N/N
>55/ C459100 1 1022 10221073	3^	GENRL	Injection site pain/ Mild Injection Site Pain	1	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
		MUSC	Muscle spasms/ Generalized Muscle Cramps	1	27AUG2020	2/1	2	Yes		NA	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Generalized Myalgias	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/Y
>55/ C459100 1 1022 10221075	3^	GENRL	Injection site pain/ Mild Injection Site pain	1	27AUG2020	1/1	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Injection site pain/ Mild Injection site pain	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1022 10221077	3^	GENRL	Injection site pain/ Mild Injection site pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 1 1022 10221085	3^	MUSC	Myalgia/ Myalgias (generalized)	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N
		RESP	Throat irritation/ Mild scratchy throat	2	18SEP2020	3/1	1	No	O	NA	R (18SEP2020)	N/N
>55/ C459100 1 1022 10221086	3^	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 1 1022 10221089	3^	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
			Injection site pain/ Pain At the injection site	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1022 10221091	3^	GENRL	Chills/ Mild Chills	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ Fever	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ Moderate Headache	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1022 10221092	3^	NERV	Syncope/ Episode of syncope	1	12SEP2020	16/1	3	No	CD	NA	R (12SEP2020)	N/N
>55/ C459100 1 1022 10221095	3^	GENRL	Injection site pain/ Mild Injection Site Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/Y
		GENRL	Chills/ Moderate Chills	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
			Injection site pain/ Moderate injection site pain	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ Moderate Headache	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1022 10221096	3^	CARD	Atrial fibrillation/ Exacerbation of Paroxysmal Atrial Fibrillation	2	26SEP2020	4/C	2	No	O	NA/TCN	N	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Moderate Injection site pain	1	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1022 10221097 >55/ C459100	3^	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
1 1022 10221102 >55/ C459100	3^	GENRL	Injection site pain/ Moderate Injection site pain	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
1 1022 10221104		GENRL	Injection site pain/ Mild Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ Mild Headache	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1022 10221107	3^	GENRL	Injection site pain/ Mild Injection site pain	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 1 1022 10221116	3^	GENRL	Injection site pain/ injection site pain*		02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Fatigue/ Moderate Fatigue	2	23SEP2020	2/C	2	Yes		NA	N	N/N
			Injection site pain/ Moderate injection site pain	2	23SEP2020	2/C	2	Yes		NA	N	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Mild Injection site pain*		03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1022 10221118		NERV	Headache/ Moderate Headache	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	25SEP2020	23/1	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ Mild Headache	1	25SEP2020	23/1	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1022 10221132	3^	GENRL	Chills/ Chills	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
			Fatigue/ Fatigue	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ Mild Injection Site Pain	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
		MUSC	Arthralgia/ Arthralgias	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C459100 1 1022 10221140	3^	GENRL	Injection site pain/ Mild Injection site pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Fatigue/ Mild fatigue	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Fatigue/ Mild Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1022 10221145	3^	GENRL	Injection site pain/ Mild Injection site pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Chills/ Mild Chills	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1022 10221148	3^	GENRL	Fatigue/ Moderate Fatigue	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
			Fatigue/ Mild Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1022 10221151	3^	MUSC	Injection site pain/ Moderate Injection Site Pain	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
			Myalgia/ Generalized Myalgias	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1022 10221151	3^	INV	Hepatitis C antibody positive/ Positive Hepatitis C antibody test	2	19OCT2020	19/C	1	No	O	NA	N	N/N
>55/ C459100 1 1022 10221152	3^	GENRL	Injection site pain/ Injection site pain	1	11SEP2020	1/7	1	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ Pain at the injection site	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
			Injection site swelling/ Swelling at the injection site	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1022 10221154	3^	GENRL	Injection site pain/ Mild Injection Site Pain	2	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Injection site erythema/ Mild Erythema injection site	2	06OCT2020	2/4	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1022 10221155	3^	NERV	Headache/ Headache (worse than baseline)	2	11OCT2020	7/2	1	Yes		NA	R (12OCT2020)	N/N
>55/ C459100 1 1022 10221157	3^	GENRL	Chills/ Chills	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
			Fatigue/ Fatigue	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
		NERV	Balance disorder/ Loss Of Balance	2	06OCT2020	2/2	2	No	O	NA	R (07OCT2020)	N/N
		MUSC	Bursitis/ Left Trochanteric Bursitis	2	10OCT2020	6/C	3	No	O	NA/TC/TCN	N	N/N
>55/ C459100 1 1022 10221160	3^	GENRL	Chills/ Moderate Chills	1	17SEP2020	3/2	2	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ Moderate Headache	1	17SEP2020	3/C	2	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INFEC	Hordeolum/ Hordeolum Right Lower Lid	1	19SEP2020	5/22	1	No	O	NA/TCN	R (10OCT2020)	N/N
>55/ C459100 1 1022 10221161	3^	GASTR	Diarrhoea/ Diarrhea	1	04OCT2020	5/4	1	No	CD	NA	R (07OCT2020)	N/N
>55/ C459100 1 1022 10221165	3^	GENRL	Injection site pain/ Mild Injection Site Pain	1	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/Y
		GENRL	Injection site pain/ Mild Injection Site Pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 1022 10221168	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1022 10221169	3^	GENRL	Injection site pain/ Mild Injection site pain	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1022 10221173	3^	GENRL	Injection site pain/ Mild Injection Site Pain	1	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Chills/ Mild Chills	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
		GENRL	Fatigue/ Mild Fatigue	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1022 10221176	3^	GASTR	Nausea/ Mild Nausea	1	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/Y
		GENRL	Fatigue/ Mild Fatigue	1	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/Y
			Injection site pain/ Mild Injection Site Pain	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/Y
		GENRL	Chills/ Moderate Chills	2	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N
			Fatigue/ Moderate fatigue	2	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ Moderate Generalized Myalgias	2	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N
		GENRL	Injection site pain/ Mild injection Site Pain	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 1022 10221177	3^	GENRL	Chills/ Chills	1	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1024 10241031	3^	GENRL	Fatigue/ Tired	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
			Pain/ Generalized Aches	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	1	18AUG2020	1/1	1	Yes		NA	R (18AUG2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1024 10241034 >55/ C459100	3^	EYE	Retinal detachment/ Retinal Detachment Left eye	1	14SEP2020	21/C	2	No	O	NA	N	N/N
1 1024 10241077 >55/ C459100	3^	GENRL	Pain/ generalized body aches	2	19SEP2020	2/2	1	Yes		NA/TCN	R (20SEP2020)	N/N
1 1024 10241097 >55/ C459100	3^	EYE	Cataract/ Bilateral Cataracts	2	SEP2020	1/C	2	No	O	NA/TCN	N	N/N
1 1027 10271007 >55/ C459100	3^	NEOPL	Acute myeloid leukaemia/ Acute Myeloid Leukemia	2	08NOV2020	58/C	3	No	O	NA	N	Y/N
1 1027 10271054 >55/ C459100	3^	GENRL	Injection site pruritus/ Intermittent Itching at Injection Site (Left arm)	2	01OCT2020	15/27	1	Yes		NA	R (27OCT2020)	N/N
1 1027 10271095 >55/ C459100	3^	GASTR	Nausea/ NAUSEA	1	07SEP2020	11/1	1	No	O	NA	R (07SEP2020)	N/N
1 1027 10271099		RESP	Oropharyngeal pain/ MILD SORE THROAT	1	07SEP2020	11/1	1	No	O	NA	R (07SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1027 10271132	3^	NERV	Headache/ Headache	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1027 10271138	3^	MUSC	Osteoporosis/ Osteoporosis	1	18SEP2020	16/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1027 10271144	3^	GENRL	Pyrexia/ Fever	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ Headache	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1027 10271153	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	2	02NOV2020	33/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1027 10271166	3^	GASTR	Nausea/ Nausea	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Chills/ Chills	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
		NERV	Headache/ Headache	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1028 10281006	3^	INV	Body temperature increased/ increased body temperature	1	03SEP2020	18/1	2	No	O	NA	R (03SEP2020)	N/N
>55/ C459100 1 1028 10281011	3^	GENRL	Injection site pain/ Injection Site Pain, Left Arm	1	19AUG2020	2/3	2	Yes		NA	R (21AUG2020)	N/N
>55/ C459100 1 1028 10281012	3^	MUSC	Trigger finger/ RIGHT MIDDLE DIGIT TRIGGER FINGER	2	01OCT2020	16/C	2	No	O	NA	N	N/N
>55/ C459100 1 1028 10281014	3^	GENRL	Injection site pain/ sore arm right deltoid injection site	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
		NERV	Headache/ headache	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 1 1028 10281032	3^	GENRL	Injection site pain/ Left Arm Injection Site Pain	1	20AUG2020	1/3	2	Yes		NA	R (22AUG2020)	N/Y
		INJ&P	Joint dislocation/ Left Shoulder Dislocation	2	13SEP2020	3/1	2	No	O	NA	R (13SEP2020)	N/N
		MUSC	Muscle spasms/ Left Arm Muscle Spasms	2	13SEP2020	3/C	2	No	O	NA	N	N/N
		MUSC	Muscle spasms/ Left Arm Charley Horse	2	15SEP2020	5/1	2	No	O	NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INJ&P	Muscle contusion/ Left Bicep Bruise	2	18SEP2020	8/4	2	No	O	NA	R (21SEP2020)	N/N
>55/ C459100 1 1028 10281034	3^	GENRL	Chills/ chills	2	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N
		MUSC	Neck pain/ neck pain	2	01OCT2020	21/C	2	Yes		NA/TC	N	N/N
>55/ C459100 1 1028 10281039	3^	GENRL	Injection site pain/ left arm soreness at injection site	1	21AUG2020	1/4	2	Yes		NA	R (24AUG2020)	N/N
		INJ&P	Fall/ accidental fall	1	10SEP2020	21/1	2	No	O	NA	R (10SEP2020)	N/N
			Skin abrasion/ abrasion left forearm	1	10SEP2020	21/34	2	No	O	NA	R (13OCT2020)	N/N
			Skin abrasion/ abrasion right elbow	1	10SEP2020	21/34	2	No	O	NA	R (13OCT2020)	N/N
			Skin abrasion/ abrasion right side flank	1	10SEP2020	21/34	2	No	O	NA	R (13OCT2020)	N/N
>55/ C459100 1 1028 10281046	3^	GENRL	Injection site pain/ left deltoid soreness at injection site	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1028 10281057	3^	GENRL	Fatigue/ Fatigue	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INJ&P	Wound/ puncture wound	1	30AUG2020	6/1	2	No	O	NA	R (30AUG2020)	N/N
>55/ C459100 1 1028 10281073	3^	GENRL	Injection site pain/ LEFT ARM SORENESS AT INJECTION SITE	1	28AUG2020	2/1	2	Yes		NA	R (28AUG2020)	N/N
		GENRL	Injection site pain/ left arm pain at injection site	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site rash/ left arm rash at injection site	2	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1028 10281082	3^	GENRL	Injection site pain/ left arm soreness at injection site	1	31AUG2020	1/8	2	Yes		NA	R (07SEP2020)	N/N
		GENRL	Chills/ Body Chills	2	22SEP2020	2/C	2	Yes		NA	N	N/N
			Pain/ generalized Body Aches	2	22SEP2020	2/C	2	Yes		NA	N	N/N
			Pyrexia/ fever	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1028 10281092	3^	INV	Body temperature increased/ elevated temp	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1028 10281099	3^	GASTR	Constipation/ constipation	2	14OCT2020	23/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1028 10281108	3^	MUSC	Myalgia/ muscle aches	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1028 10281109	3^	GENRL	Chills/ chills	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N
			Pyrexia/ fever	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ headache	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1028 10281115	3^	GENRL	Injection site bruising/ Left Arm Injection Site Bruise	1	03SEP2020	1/3	2	Yes		NA/TCN	R (05SEP2020)	N/N
			Injection site pain/ Left Arm Injection Site Pain	1	03SEP2020	1/3	2	Yes		NA	R (05SEP2020)	N/N
		GENRL	Pain/ Generalized Body Aches	1	04SEP2020	2/2	2	Yes		NA	R (05SEP2020)	N/N
		GASTR	Oral pain/ Mouth Pain	1	05SEP2020	3/61	2	No	O	NA/TCN	R (04NOV2020)	N/N
		INJ&P	Tooth fracture/ Broken Tooth, Upper Left	1	05SEP2020	3/17	2	No	O	NA/TC/TCN	R (21SEP2020)	N/N
		GENRL	Injection site bruising/ injection site bruise left arm	2	25SEP2020	2/4	2	Yes		NA	R (28SEP2020)	N/N
			Injection site erythema/ injection site redness left arm	2	25SEP2020	2/4	2	Yes		NA	R (28SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1028 10281142	3^	GENRL	Injection site pain/ left arm injection site pain	2	25SEP2020	2/4	2	Yes		NA/TC	R (28SEP2020)	N/N
			Injection site reaction/ injection site welt left arm	2	25SEP2020	2/4	2	Yes		NA	R (28SEP2020)	N/N
			Injection site pain/ RIGHT ARM SORENESS AT INJECTION SITE	1	07SEP2020	1/3	2	Yes		NA	R (09SEP2020)	N/N
			Pain/ BODY ACHES	1	07SEP2020	1/3	2	Yes		NA	R (09SEP2020)	N/N
			Injection site pain/ RIGHT ARM SORENESS AT INJECTION SITE	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
>55/ C459100 1 1028 10281147	3^	GENRL	Pain/ BODY ACHES	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
			Pyrexia/ fever	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
			NERV	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1028 10281151	3^	MUSC	Pain in extremity/ right arm soreness	1	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 1 1028 10281157	3^	EYE	Ocular hyperaemia/ bloodshot eyes bilateral	1	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1028 10281175	3^	GENRL	Fatigue/ fatigue	2	29SEP2020	1/4	2	Yes		NA	R (02OCT2020)	N/N
		GENRL	Pain/ general body aches	1	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1028 10281193	3^	INV	Body temperature increased/ elevated body temperature	2	06OCT2020	2/1	2	Yes		NA	R (06OCT2020)	N/N
		NERV	Dizziness/ Lightheaded	1	16SEP2020	1/1	2	No	O	NA	R (16SEP2020)	N/Y
>55/ C459100 1 1028 10281204	3^	GENRL	Pyrexia/ fever	2	14OCT2020	7/2	2	Yes		NA	R (15OCT2020)	N/N
		GENRL	Injection site pain/ sore left arm at injection site	2	09OCT2020	1/3	2	Yes		NA	R (11OCT2020)	N/N
>55/ C459100 1 1028 10281206	3^	GENRL	Pyrexia/ fever	2	10OCT2020	2/3	2	Yes		NA/TC	R (12OCT2020)	N/N
		GENRL	Malaise/ general malaise	1	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pruritus/ injection site itching left arm	2	09OCT2020	1/7	2	Yes		NA	R (15OCT2020)	N/N
			Malaise/ general malaise	2	09OCT2020	1/3	2	Yes		NA	R (11OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1028 10281215	3^	GENRL	Malaise/ general malaise	1	23SEP2020	3/2	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Malaise/ general malaise	2	14OCT2020	3/2	2	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1028 10281218	3^	MUSC	Arthralgia/ Right Elbow Pain	2	24OCT2020	12/C	2	No	O	NA	N	N/N
>55/ C459100 1 1028 10281234	3^	INFEC	Sinusitis/ sinus infection	2	29OCT2020	14/7	2	No	O	NA/TC	R (04NOV2020)	N/N
>55/ C459100 1 1028 10281235	3^	GENRL	Chills/ chills	2	17OCT2020	3/2	2	Yes		NA	R (18OCT2020)	N/N
		INV	Pain/ achiness	2	17OCT2020	3/2	2	Yes		NA	R (18OCT2020)	N/N
>55/ C459100 1 1036 10361002	3^	GENRL	Body temperature increased/ elevated body temperature	2	17OCT2020	3/2	2	Yes		NA	R (18OCT2020)	N/N
			Injection site erythema/ Redness at injection site beginning two days post injection	2	10SEP2020	3/27	1	Yes		NA	R (06OCT2020)	N/N
			Injection site pain/ soreness at the injection site beginning second day post injection	2	10SEP2020	3/27	1	Yes		NA	R (06OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Injection site swelling/ Swelling at injection site beginning two days post injection	2	10SEP2020	3/27	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1036 10361028	3^	GENRL	Injection site pain/ muscle soreness at injection site, left deltoid	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
			Injection site swelling/ left deltoid swelling at injection site	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
>55/ C459100 1 1036 10361034	3^	GENRL	Chills/ Chills; for a period of 24 hrs before going away. No OTC meds taken.	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
			Pyrexia/ Fever; 101.4 day after 2nd injection. Fever rose to 101.7. Fever gone by next day. No OTC meds taken	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
		NERV	Lethargy/ Lethary; stated after 2nd injection felt run down & tired for 24 hrs. No OTC meds taken.	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1036 10361116	3^	GENRL	Pain/ Body aches	2	29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N
		NERV	Headache/ Headache	2	29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1037 10371004	3^	SKIN	Alopecia/ HAIR LOSS	2	12SEP2020	4/C	1	No	O	NA	N	N/N
>55/ C459100 1 1037 10371009	3^	GENRL	Fatigue/ FATIGUE	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1037 10371012	3^	GENRL	Pyrexia/ LOW GRADE FEVER	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1037 10371013	3^	GASTR	Vomiting/ VOMITING	2	28SEP2020	21/1	2	No	O	NA	R (28SEP2020)	N/N
>55/ C459100 1 1037 10371019	3^	GASTR	Diarrhoea/ DIARRHEA	1	21AUG2020	3/3	2	Yes		NA/TC	R (23AUG2020)	N/N
		MUSC	Arthralgia/ BILATERAL SHOULDER PAIN	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
		NERV	Somnolence/ MORNING SLEEPINESS	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1037 10371020	3^	GASTR	Constipation/ CONSTIPATION	1	01SEP2020	14/8	1	No	O	NA	R (08SEP2020)	N/N
>55/ C459100 1 1037 10371034	3^	INJ&P	Arthropod bite/ INSECT BITE	1	07SEP2020	19/5	2	No	O	NA/TC	R (11SEP2020)	N/N
>55/ C459100 1 1037 10371055	3^	GENRL	Chills/ CHILLS	2	15SEP2020	2/4	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1037 10371070	3^	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1037 10371075	3^	GENRL	Pain/ BODY ACHES	2	15SEP2020	1/1	1	Yes		NA/TC	R (15SEP2020)	N/N
		INFEC	Influenza/ MILD FLU SYMPTOMS	2	15SEP2020	1/1	1	Yes		NA/TC	R (15SEP2020)	N/N
>55/ C459100 1 1037 10371094	3^	GENRL	Fatigue/ FATIGUE	1	31AUG2020	1/2	1	Yes		NA/TC	R (01SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	31AUG2020	1/2	1	Yes		NA/TC	R (01SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1037 10371095	3^	NERV	Headache/ HEADACHE	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		GASTR	Nausea/ NAUSEA	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1037 10371099	3^	NERV	Headache/ HEADACHE	2	21SEP2020	1/4	3	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Muscle spasms/ NECK SPASMS	1	02SEP2020	2/2	1	No	O	NA	R (03SEP2020)	N/N
		GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	25SEP2020	3/4	1	Yes		NA	R (28SEP2020)	N/N
>55/ C459100 1 1037 10371105	3^	SKIN	Night sweats/ Nocturnal sweats	2	22SEP2020	2/3	2	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1037 10371108	3^	INJ&P	Muscle strain/ LUMBAR SACRUM STRAIN	1	03SEP2020	3/2	1	No	O	NA/TCN	R (04SEP2020)	N/N
>55/ C459100	3^	GENRL	Chills/ chills	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1037 10371113		GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1037 10371119	3^	GASTR	Diarrhoea/ DIARRHEA	1	03SEP2020	2/18	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Chills/ CHILLS	1	03SEP2020	2/18	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1037 10371135	3^	INFEC	Urinary tract infection/ URINARY TRACK INFECTION	2	25OCT2020	32/4	2	No	O	NA/TC	R (28OCT2020)	N/N
>55/ C459100 1 1037 10371160	3^	GASTR	Nausea/ Nausea	1	10SEP2020	3/4	2	No	O	NA/TC	R (13SEP2020)	N/N
		GENRL	Fatigue/ Tired (fatigue)	1	10SEP2020	3/4	2	No	O	NA/TC	R (13SEP2020)	N/N
		INFEC	Urinary tract infection/ Urinary tract infection	1	10SEP2020	3/11	2	No	O	NA/TC	R (20SEP2020)	N/N
		NERV	Headache/ Headache	1	10SEP2020	3/4	2	No	O	NA/TC	R (13SEP2020)	N/N
		MUSC	Myalgia/ Leg muscle pain	2	30SEP2020	3/2	2	No	O	NA/TC	R (01OCT2020)	N/N
		INFEC	Skin infection/ SKIN INFECTION Bilateral Arms and Legs	2	03OCT2020	6/11	2	No	O	NA/TC	R (13OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1037 10371167	3^	GENRL	Influenza like illness/ Flu-like Symptoms	2	02OCT2020	2/2	2	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100 1 1037 10371174	3^	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1037 10371177	3^	INFEC	Ear infection/ LEFT EAR INFECTION	1	04OCT2020	26/6	2	No	O	NA/TC	R (09OCT2020)	N/N
>55/ C459100 1 1037 10371178	3^	INJ&P	Contusion/ BRUISE RIGHT ARM	2	11OCT2020	11/C	1	No	O	NA	N	N/N
>55/ C459100 1 1037 10371181	3^	MUSC	Myalgia/ Muscle aches	2	01OCT2020	1/2	2	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1037 10371185	3^	INJ&P	Pain in extremity/ Left arm pain Rib fracture/ RIB FRACTURE	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1037 10371211	3^	GENRL	Chills/ CHILLS	1	13SEP2020	4/12	1	No	O	NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1037 10371211	3^	GENRL	Chills/ CHILLS	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1037 10371239	3^	MUSC	Injection site pain/ PAIN AT INJECTION SITE	1	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
			Myalgia/ MUSCLE ACHES	1	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		GENRL	Injection site pain/ PAIN AT INJECTIO SITE	1	22SEP2020	8/1	2	Yes		NA	R (22SEP2020)	N/N
			Myalgia/ MUSCLE PAIN	1	22SEP2020	8/1	2	Yes		NA/TC	R (22SEP2020)	N/N
		NERV	Lethargy/ LETHARGY	1	22SEP2020	8/1	2	Yes		NA	R (22SEP2020)	N/N
			Injection site pain/ PAIN AT INJECTION SITE	2	06OCT2020	2/1	2	Yes		NA	R (06OCT2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	06OCT2020	2/1	2	Yes		NA/TC	R (06OCT2020)	N/N
			Lethargy/ LETHARGY	2	06OCT2020	2/1	2	Yes		NA	R (06OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
			Muscle spasms/ MUSCLE CRAMPS	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
>55/ C459100 1 1037 10371252	3^	GASTR	Nausea/ Nausea	1	07OCT2020	17/1	1	No	O	NA	R (07OCT2020)	N/N
		UNC	FATIGUE@@/ FATIGUE	2	14OCT2020	2/2	1	Yes		P	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1037 10371261	3^	GENRL	FEVER@@/ FEVER	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
			MUSCLE ACHES@@/ MUSCLE ACHES	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
			Influenza like illness/ FLU LIKE SYMPTOMS	2	14OCT2020	1/2	2	Yes		NA/TC	R (15OCT2020)	N/N
>55/ C459100 1 1037 10371263	3^	GENRL	Chills/ CHILLS	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 1037 10371264	3^	INFEC	Fatigue/ FATIGUE	2	13OCT2020	2/2	2	Yes		NA/TC	R (14OCT2020)	N/N
			Pyrexia/ FEVER	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
			Vaginal infection/ VAGINAL INFECTION	1	11OCT2020	20/1	1	No	O	NA/TC	R (11OCT2020)	N/N
>55/ C459100 1 1037 10371295	3^	GENRL	Pyrexia/ ASYMPTOMATIC LOW GRADE FEVER OF 100.4 F*		25SEP2020	-3/1	1	No	O	NA	R (25SEP2020)	N/N
>55/ C459100	3^	GENRL	Pyrexia/ FEVER	2	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
		GENRL	Pyrexia/ FEVER	2	27OCT2020	2/1	2	Yes		NA/TC	R (27OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1037 10371320 >55/ C459100 1 1038 10381007	3^	GASTR	Diarrhoea/ Diarrhea	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N
>55/ C459100 1 1038 10381046	3^	GENRL	Injection site pain/ Injection site tenderness	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Fatigue/ fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1038 10381074	3^	GENRL	Injection site pain/ Injection Site Soreness	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ injection site tenderness	1	23SEP2020	23/2	1	Yes		NA	R (24SEP2020)	N/N
		INV	Body temperature increased/ Increased Body Temperature (100F)	1	23SEP2020	23/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1038 10381101	3^	GENRL	Injection site pain/ Injection site tenderness	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Ischaemic stroke/ Acute Ischemic Stroke	2	04OCT2020	7/3	2	No	O	NA	R (06OCT2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1038 10381108	3^	GENRL	Injection site pain/ Injection Site Tenderness	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1038 10381126	3^	GASTR	Diarrhoea/ Diarrhea	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
			Nausea/ Nausea	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Pain/ Body Aches	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		NERV	Headache/ Headache	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1038 10381134	3^	GENRL	Injection site pain/ injection site tenderness	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		SURG	Skin neoplasm excision/ basal cell carcinoma removed from L side of nose	1	01OCT2020	11/1	1	No	O	NA	R (01OCT2020)	N/N
		GENRL	Pyrexia/ fever	2	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1039 10391010	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
		INJ&P	Contusion/ right arm bruising	1	21AUG2020	1/13	1	Yes		NA	R (02SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ injection site pain	2	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
		GENRL	Pyrexia/ FEVER	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C459100 1 1039 10391013	3^	GASTR	Diarrhoea/ diarrhea	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
>55/ C459100 1 1039 10391015	3^	INV	Monocyte count increased/ monocyte level elevated	2	30SEP2020	15/C	1	No	O	NA	N	N/N
>55/ C459100 1 1039 10391019	3^	GASTR	Colitis microscopic/ EXACERBATION OF LYMPHOCYTIC- PLASMACYTIC COLITIS	1	29AUG2020	6/29	2	No	O	NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1039 10391024	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
		MUSC	Arthralgia/ INCREASED BILATERAL KNEE PAIN	2	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N
			Pain in extremity/ RIGHT ARM SORENESS	2	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1039 10391027	3^	EAR	Ear pain/ left ear pain	1	15SEP2020	22/1	1	No	O	NA/TC	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1039 10391031	3^	GENRL	Pain/ generalized aching	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Fatigue/ fatigue	1	28AUG2020	3/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 1 1039 10391032	3^	GENRL	Injection site swelling/ swelling at injection site	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		MUSC	Pain in extremity/ left arm pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
>55/ C459100 1 1039 10391041	3^	GENRL	Injection site pain/ left arm soreness at injection site	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N
>55/ C459100 1 1039 10391046	3^	GENRL	Chills/ mild chills	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
			Fatigue/ fatigue	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ fever	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Muscle spasms/ leg muscle cramping	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			Pain in extremity/ Left upper arm soreness	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1039 10391047	3^	NERV	Headache/ mild headache	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		PSYCH	Insomnia/ difficulty sleeping	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ Injection site, left upper arm pain	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
		EYE	Vitreous detachment/ detached Left vitreous	2	07OCT2020	20/C	2	No	O	NA	RG	N/N
>55/ C459100 1 1039 10391055	3^	INV	Body temperature increased/ temperature elevation	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
>55/ C459100 1 1039 10391056	3^	MUSC	Pain in extremity/ bilateral upper arm pain	2	24SEP2020	4/1	1	No	O	NA	R (24SEP2020)	N/N
>55/ C459100 1 1039 10391061	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
>55/ C459100 1 1039 10391077	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ injection site soreness	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ chills	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
			Pain/ body aches	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1039 10391078	3^	SKIN	Pseudofolliculitis/ Pseudofolliculitis Barbae left axilla	1	23SEP2020	22/12	1	No	O	NA	R (04OCT2020)	N/N
>55/ C459100 1 1039 10391079	3^	GASTR	Nausea/ nausea	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Chills/ chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Arthralgia/ arthlagias	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N
		NERV	Headache/ headache	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1039 10391089	3^	GASTR	Nausea/ nausea	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Pain/ generalized aches	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
			Pyrexia/ fever	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1039 10391092	3^	GENRL	Injection site pain/ injection site pain	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
			Pyrexia/ fever	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ injection site soreness	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
			Pyrexia/ fever	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
		GENRL	Chills/ chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
			Pain/ generalized aching	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 1 1039 10391095	3^	MUSC	Pain in extremity/ right big toe pain	1	13SEP2020	10/7	1	No	O	NA	R (19SEP2020)	N/N
>55/ C459100 1 1039 10391107	3^	GENRL	Pain/ generalized aching	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
			NERV	Headache/ headache	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)
		GENRL	Pain/ generalized aching	2	29SEP2020	1/4	1	Yes		NA	R (02OCT2020)	N/N
			NERV	Headache/ headache	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1039 10391122	3^	INJ&P	Fall/ Fell on left arm while biking	2	13OCT2020	15/14	1	No	CD	NA/TC	R (26OCT2020)	N/N
		INJ&P	Skin abrasion/ abrasions left arm (upper arm and forearm)	2	26OCT2020	28/1	1	No	O	NA	R (26OCT2020)	N/N
		SKIN	Dermatitis contact/ contact dermatitis left forearm arm	2	27OCT2020	29/C	1	No	O	NA/TC	N	N/N
		GENRL	Chills/ chills	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
			Injection site pain/ injection site pain	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Myalgia/ myalgias	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
>55/ C459100 1 1039 10391123	3^	NERV	Headache/ headache	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Chills/ chills	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ myalgias	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Chills/ chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1039 10391129	3^	NERV	Pain/ aches	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Pyrexia/ fever	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
			Headache/ headache	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	14OCT2020	2/C	1	Yes		NA	RG	N/N
		GENRL	Chills/ chills	2	15OCT2020	3/1	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Pyrexia/ fever	2	15OCT2020	3/1	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1039 10391131	3^	GENRL	Myalgia/ myalgias	2	15OCT2020	3/C	1	Yes		NA/TCN	RG	N/N
		GENRL	Pain/ generalized aching	1	12SEP2020	2/2	2	Yes		NA/TC	R (13SEP2020)	N/N
		GENRL	Pain/ generalized aching	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100	3^	NERV	Headache/ headache	2	03OCT2020	2/8	1	Yes		NA/TC	R (10OCT2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1039 10391141 >55/ C459100 1 1039 10391148	3^	GENRL	Injection site pain/ injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Pain in extremity/ bilateral thigh pain	2	16OCT2020	9/C	1	No	O	NA	RG	N/N
			Plantar fasciitis/ recurrence of plantar fasciitis	2	16OCT2020	9/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1039 10391155	3^	GENRL	Injection site pain/ injection site aching	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Injection site pain/ inject site soreness	2	15OCT2020	1/3	1	Yes		NA/TC	R (17OCT2020)	N/N
>55/ C459100 1 1039 10391158	3^	NERV	Headache/ headaches	1	28SEP2020	4/2	1	Yes		NA	R (29SEP2020)	N/N
>55/ C459100 1 1039 10391184	3^	GENRL	Injection site bruising/ injection site bruising	2	29OCT2020	1/C	1	Yes		NA	RG	N/Y
		INJ&P	Muscle strain/ muscle strain, upper back	2	30OCT2020	2/3	1	No	O	NA/TC	R (01NOV2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	31OCT2020	3/C	1	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1042 10421018	3^	SKIN	Urticaria/ HIVES (Back and Inner thighs)	1	02AUG2020	3/6	1	Yes		NA/TC	R (07AUG2020)	N/N
>55/ C459100 1 1042 10421127	3^	INJ&P	Arthropod sting/ wasp sting	2	14SEP2020	6/1	1	No	O	NA/TC	R (14SEP2020)	N/N
>55/ C459100 1 1042 10421160	3^	GASTR	Diarrhoea/ Diarrhea	1	28AUG2020	3/1	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Chills/ Chills	2	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1042 10421166	3^	INJ&P	Brain contusion/ Left frontal lobe contusion	1	03SEP2020	9/30	1	No	O	NA	R (02OCT2020)	N/N
			Fall/ FALL	1	03SEP2020	9/1	1	No	O	NA/TC	R (03SEP2020)	N/N
			Pelvic fracture/ Closed Fracture of Rt Interior Pubic Ramus	1	03SEP2020	9/30	2	No	O	NA	R (02OCT2020)	N/N
			Rib fracture/ Closed Fracture of Four Ribs	1	03SEP2020	9/30	2	No	O	NA	R (02OCT2020)	N/N
			Scapula fracture/ Closed Displaced Fracture of body Right Scapula	1	03SEP2020	9/48	2	No	O	NA	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Arthralgia/ Acute Pain hip right side	1	03SEP2020	9/30	1	No	O	NA/TC	R (02OCT2020)	N/N
			Arthralgia/ Right Shoulder Pain	1	03SEP2020	9/48	1	No	O	NA/TC	R (20OCT2020)	N/N
			Mobility decreased/ Decreased Mobility	1	03SEP2020	9/48	1	No	O	NA	R (20OCT2020)	N/N
			Muscle spasms/ Muscle Spasm	1	03SEP2020	9/30	2	No	O	NA	R (02OCT2020)	N/N
		NERV	Subarachnoid haemorrhage/ SUBARACHNOID HEMORRAGE	1	03SEP2020	9/C	3	No	O	NA/TC	RG	Y/N
>55/ C459100 1 1042 10421171	3^	BLOOD	Iron deficiency anaemia/ iron deficient anemia worsening	2	07OCT2020	17/C	3	No	O	NA	N	N/N
>55/ C459100 1 1042 10421202	3^	GENRL	Pyrexia/ Fever	2	29SEP2020	2/1	2	Yes		NA/TC	R (29SEP2020)	N/N
>55/ C459100 1 1042 10421208	3^	RESP	Oropharyngeal pain/ Sore Throat	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
			Rhinorrhoea/ Nasal Discharge	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1042 10421212	3^	GENRL	Fatigue/ Fatigue	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1042 10421215	3^	RESP	Cough/ New or Increased Cough	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
		GENRL	Chills/ Chills	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
			Fatigue/ Fatigue	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1044 10441003	3^	INFEC	Pyrexia/ Low Grade Fever	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
			Acute sinusitis/ Acute Sinusitis	2	13OCT2020	20/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1044 10441013	3^	INFEC	Urinary tract infection/ UTI	1	03SEP2020	16/6	1	No	O	NA/TC	R (08SEP2020)	N/N
>55/ C459100 1 1044 10441014	3^	INV	Blood pressure increased/ Elevated Blood Pressure	1	08SEP2020	21/1	2	No	O	NA/TC	R (08SEP2020)	N/N
>55/ C459100 1 1044 10441016	3^	RESP	Upper-airway cough syndrome/ post nasal drip	2	08OCT2020	31/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1044 10441017	3^	MUSC	Myalgia/ generalized Myalgia	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1044 10441025	3^	GENRL	Fatigue/ fatigue	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N
		NERV	Headache/ headache	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
>55/ C459100 1 1044 10441062	3^	GENRL	Chills/ chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
			Injection site pain/ Injection site pain	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1044 10441066	3^	GENRL	Injection site haematoma/ injection site hematoma	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
>55/ C459100 1 1044 10441067	3^	GENRL	Pyrexia/ fever	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
>55/ C459100 1 1044 10441073	3^	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ fever	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ generalized Myalgia	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1044 10441078	3^	GENRL	Injection site haematoma/ INJECTION SITE HEMATOMA	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/Y
>55/ C459100 1 1044 10441080	3^	INJ&P	Ligament sprain/ left ankle sprain	1	17SEP2020	14/24	1	No	O	NA/TC	R (10OCT2020)	N/N
>55/ C459100 1 1044 10441082	3^	GENRL	Fatigue/ fatigue	2	02OCT2020	10/2	1	No	O	NA	R (03OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	02OCT2020	10/2	1	No	O	NA/TC	R (03OCT2020)	N/N
>55/ C459100 1 1044 10441090	3^	GASTR	Constipation/ constipation	1	09SEP2020	4/6	1	No	O	NA/TC	R (14SEP2020)	N/N
		INFEC	Cystitis/ Bladder Infection	1	24SEP2020	19/9	1	No	O	NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1044 10441093	3^	INJ&P	Muscle injury/ Muscle Sprain (Right Leg)	1	23SEP2020	16/C	1	No	O	NA/TC	RG	N/N
		INJ&P	Overdose/ Heroin Overdose	2	23OCT2020	26/2	4	No	O	NA/TC	R (24OCT2020)	Y/N
		METAB	Hypokalaemia/ Hypokalemia	2	23OCT2020	26/2	2	No	O	NA/TC	R (24OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Hypomagnesaemia/ Hypomagnesemia	2	23OCT2020	26/2	2	No	O	NA/TC	R (24OCT2020)	N/N
>55/ C459100 1 1044 10441104	3^	GASTR	Diarrhoea/ Diarrhea	1	20SEP2020	11/1	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1044 10441106	3^	INV	Low density lipoprotein increased/ elevated ldl	2	09OCT2020	4/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1044 10441110	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	2	01OCT2020	2/10	1	No	O	NA/TC	R (10OCT2020)	N/N
>55/ C459100 1 1044 10441116	3^	MUSC	Arthralgia/ Worsening of Shoulder Pain (Left)	1	23SEP2020	10/9	2	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1044 10441120	3^	GENRL	Chills/ chills	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
			Injection site pain/ injection site pain	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
			Pyrexia/ fever	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1044 10441128	3^	GENRL	Fatigue/ fatigue	2	14OCT2020	2/4	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 1044 10441131	3^	GASTR	Diarrhoea/ Diarrhea	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	15OCT2020	2/5	1	Yes		NA	R (19OCT2020)	N/N
		NERV	Headache/ Headache	2	15OCT2020	2/4	1	Yes		NA/TC	R (18OCT2020)	N/N
		SKIN	Rash/ Rash (hands & feet)	2	16OCT2020	3/4	1	No	O	NA	R (19OCT2020)	N/N
		GENRL	Chest discomfort/ Pressure in Chest	2	18OCT2020	5/1	2	No	O	NA	R (18OCT2020)	N/N
		GASTR	Nausea/ Nausea	2	19OCT2020	6/2	1	No	O	NA	R (20OCT2020)	N/N
>55/ C459100 1 1044 10441134	3^	GENRL	Injection site pain/ injection site pain	2	14OCT2020	1/6	1	Yes		NA	R (19OCT2020)	N/N
		NERV	Headache/ headache	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100	3^	GENRL	Fatigue/ fatigue	2	14OCT2020	1/C	1	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1044 10441135			Injection site pain/ injection site pain	2	14OCT2020	1/C	1	Yes		NA	RG	N/N
		GENRL	Pyrexia/ fever	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
>55/ C459100 1 1044 10441138	3^	VASC	Hypertension/ Hypertension	2	06NOV2020	25/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1044 10441145	3^	GENRL	Chills/ chills	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		NERV	Headache/ headache	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1044 10441149	3^	GENRL	Chills/ chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
			Fatigue/ Fatigue	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
			Injection site pain/ Injection Site Pain	2	16OCT2020	2/C	1	Yes		NA	N	N/N
			Pyrexia/ Fever	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1044 10441150	3^	INFEC	Cystitis/ bladder infection	1	30SEP2020	6/12	1	No	O	NA/TC	R (11OCT2020)	N/N
		NERV	Dizziness/ dizzines	2	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1044 10441169	3^	MUSC	Myalgia/ muscle aches	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		NERV	Headache/ headache	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
>55/ C459100 1 1046 10461059	3^	GASTR	Diarrhoea/ Diarrhea	2	22SEP2020	14/2	2	No	O	NA	R (23SEP2020)	N/N
>55/ C459100 1 1046 10461138	3^	GENRL	Fatigue/ Fatigue	2	06OCT2020	18/4	1	No	O	NA	R (09OCT2020)	N/N
			Pyrexia/ Fever	2	06OCT2020	18/4	1	No	O	NA	R (09OCT2020)	N/N
		INFEC	Sinusitis/ Sinus Infection	2	06OCT2020	18/4	1	No	O	NA	R (09OCT2020)	N/N
		RESP	Sinus congestion/ SINUS CONGESTION	2	06OCT2020	18/4	1	No	O	NA	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1046 10461245	3^	MUSC	Arthralgia/ Left Shoulder Pain	1	01OCT2020	22/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1046 10461259	3^	NERV	Dizziness/ Dizziness	1	16SEP2020	3/2	1	No	O	NA	R (17SEP2020)	N/N
>55/ C459100 1 1047 10471032	3^	RESP	Productive cough/ wet cough	1	06SEP2020	16/5	1	No	O	NA	R (10SEP2020)	N/N
>55/ C459100 1 1047 10471060	3^	GENRL	Injection site discolouration/ Discoloration at injection site*		26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
			Injection site pain/ Soreness at injection site*		26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
			Pain/ Bodyaches*		26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		NERV	Headache/ Headache*		26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Pain/ Bodyaches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1047 10471063	3^	GASTR	Abdominal pain upper/ Stomach Cramps	1	09SEP2020	14/4	1	No	O	NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1047 10471090	3^	GENRL	Diarrhoea/ Diarrhea	1	09SEP2020	14/4	1	No	O	NA	R (12SEP2020)	N/N	
			GASTR	Diarrhoea/ Diarrhea	2	16SEP2020	2/4	1	Yes		NA	R (19SEP2020)	N/N
			GENRL	Chills/ Chills	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
				Pain/ Body Aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
				Pyrexia/ Fever 100.8	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1047 10471092	3^	GENRL	Injection site pain/ Pain at injection site	1	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N	
			GENRL	Chills/ Chills	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
				Pain/ Bodyaches	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
			GENRL	Chills/ chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ soreness at injection site.	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
			INV	Body temperature increased/ increased body temperature 100.1	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ injection site soreness	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1047 10471097		GENRL	Chills/ Chills	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ Fever 102	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1047 10471099	3^	GENRL	Chills/ chills	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1047 10471101	3^	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1047 10471110	3^	GASTR	Diarrhoea/ Diarrhea	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Chills/ Chills	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 1 1047 10471114	3^	GASTR	Diarrhoea/ diarrhea	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
			Nausea/ nausea	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Vomiting/ vomiting	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
			NERV	Cerebrovascular accident/ Stroke	2	18OCT2020	26/C	3	No	O	NA	RG
>55/ C459100 1 1047 10471123	3^	MUSC	Pain in extremity/ bilateral hand pain	1	04SEP2020	2/C	2	No	O	NA	N	N/N
>55/ C459100 1 1047 10471130	3^	NERV	Headache/ headache	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
		RESP	Paranasal sinus discomfort/ Sinus Pressure	2	25SEP2020	3/3	1	Yes		NA	R (27SEP2020)	N/N
		3^	RESP	Productive cough/ Wet cough	1	06SEP2020	3/5	1	No	O	NA	R (10SEP2020)
		SKIN	Rash/ Rash left upper leg	1	19SEP2020	16/4	1	No	O	NA	R (22SEP2020)	N/N
		GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Fatigue/ Fatigue	1	23SEP2020	20/2	1	Yes		NA	R (24SEP2020)	N/N
			Pain/ Body Aches	2	23SEP2020	1/C	1	Yes		NA	RG	N/N
		NERV	Headache/ Headaches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		SKIN	Night sweats/ Night Sweats	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1047 10471136	3^	GENRL	Pyrexia/ Temp 101.8	2	26SEP2020	2/1	2	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ headache	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 1 1047 10471139	3^	GASTR	Diarrhoea/ Diarrhea	2	26SEP2020	3/1	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 1 1047 10471170	3^	GENRL	Injection site pain/ injection site Left deltoid Soreness*		09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1047 10471175	3^	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/4	1	Yes		NA	R (04OCT2020)	N/N
>55/ C459100 1 1047 10471183	3^	GENRL	Injection site pain/ Soreness at injection site Left Deltoid	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
>55/ C459100 1 1047 10471184	3^	GASTR	Diarrhoea/ Diarrhea	1	02OCT2020	22/2	1	Yes		NA	R (03OCT2020)	N/N
		NERV	Presyncope/ Vagal Response/fainted	2	02OCT2020	1/1	2	Yes		NA	R (02OCT2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1047 10471185	3^	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
			Pain/ Bodyaches	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
>55/ C459100 1 1047 10471191	3^	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1047 10471194	3^	UNC	FRACTURED LEFT ELBOW@@/ Fractured Left Elbow	2	06NOV2020	19/C	2	No	O	NA	RG	N/N
>55/ C459100 1 1047 10471206	3^	NERV	Headache/ Headache	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		GASTR	Diarrhoea/ diarrhea	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/Y
			Nausea/ nausea	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/Y
		GENRL	Chills/ chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/Y
			Injection site pain/ injection site soreness	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/Y
>55/ C459100	3^	MUSC	Arthralgia/ JOINT PAIN (ELBOW)	2	30OCT2020	23/C	2	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1047 10471208			Arthralgia/ joint pain (hand)	2	30OCT2020	23/C	2	No	O	NA	N	N/N
>55/ C459100 1 1047 10471216	3^	GENRL	Fatigue/ Fatigue*		15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1047 10471224	3^	GASTR	Constipation/ constipation	2	02NOV2020	26/C	2	No	O	NA	N	N/N
		INFEC	Vulvovaginal mycotic infection/ yeast infection vaginal infection	2	04NOV2020	28/C	2	No	O	NA	N	N/N
>55/ C459100 1 1047 10471249	3^	GASTR	Nausea/ Nausea	1	23SEP2020	3/1	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Pain in extremity/ Bilateral Leg Pain	1	23SEP2020	3/5	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1047 10471250	3^	GASTR	Nausea/ nausea	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		GENRL	Pyrexia/ low grade fever 100.7	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C459100	3^	GENRL	Chills/ Chills	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1047 10471268			Injection site pain/ Right Arm Soreness at injection site	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Musculoskeletal stiffness/ Stiff Neck	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ Headache	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Muscle spasms/ Muscle Spasms Bilateral Legs	1	05OCT2020	14/1	2	No	O	NA	R (05OCT2020)	N/N
>55/ C459100 1 1047 10471274	3^	GENRL	Fatigue/ fatigue	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
			Pyrexia/ fever 100.8	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 1047 10471276	3^	INJ&P	Contusion/ Stone Bruise right Foot	1	01OCT2020	9/C	1	No	O	NA	RG	N/N
		GASTR	Nausea/ intermittent nausea	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
		NERV	Headache/ headache	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 1048 10481015	3^	GENRL	Pain/ BODY ACHES	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1048 10481016	3^	NERV	Dizziness/ LIGHTHEADEDNESS	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
			Headache/ HEADACHE	2	10SEP2020	1/8	2	Yes		NA/TC	R (17SEP2020)	N/N
		RESP	Rhinorrhoea/ RHINORRHEA	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		RESP	Rhinorrhoea/ RHINORRHEA	2	15SEP2020	6/1	1	Yes		NA	R (15SEP2020)	N/N
	GASTR	Nausea/ nausea	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Pyrexia/ fever	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	
	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	26AUG2020	2/5	1	Yes		NA	R (30AUG2020)	N/N
	>55/ C459100 1 1048 10481033	3^	INFEC	Tooth infection/ MOLAR #31 INFECTION	1	29AUG2020	5/C	2	No	O	NA/TC	N
>55/ C459100 1 1048 10481041	3^	GENRL	Injection site irritation/ SKIN IRRITATION AT INJECTION SITE	2	18SEP2020	2/5	1	Yes		NA	R (22SEP2020)	N/N
Pain/ BODY ACHES			2	18SEP2020	2/2	2	Yes		NA/TC	R (19SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1048 10481042	3^	GASTR	Diarrhoea/ diarrhea	1	02SEP2020	7/1	1	Yes		NA	R (02SEP2020)	N/N
>55/ C459100 1 1048 10481049	3^	INFEC	Herpes zoster/ SHINGLES	1	16SEP2020	20/16	2	No	O	NA/TC	R (01OCT2020)	N/N
		NERV	Post herpetic neuralgia/ POST HERPATIC NEURALGIA	1	17SEP2020	21/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1048 10481051	3^	GENRL	Fatigue/ Fatigue	2	19SEP2020	3/6	1	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ headache	2	19SEP2020	3/5	1	No	O	NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1048 10481058	3^	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
>55/ C459100 1 1048 10481060	3^	GASTR	Nausea/ Nausea	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Pain/ Body Aches	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1048 10481066	3^	NERV	Dizziness/ dizziness	1	20SEP2020	20/2	1	No	O	NA	R (21SEP2020)	N/N
>55/ C459100 1 1048 10481067	3^	GENRL	Influenza like illness/ flu like symptoms	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1048 10481084	3^	GENRL	Pain/ BODY ACHES	2	30SEP2020	9/2	2	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1048 10481087	3^	VASC	Hypertension/ worsening of hypertension	2	07OCT2020	13/C	1	No	O	NA	N	N/N
>55/ C459100 1 1048 10481090	3^	VASC	Hypertension/ WORSENING OF HYPERTENSION	1	16SEP2020	13/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1048 10481096	3^	GENRL	Malaise/ general malaise	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	08SEP2020	1/8	2	Yes		NA/TC	R (15SEP2020)	N/N
		GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	09SEP2020	2/8	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ PAIN AT INJECTION	2	01OCT2020	2/6	1	Yes		NA	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ HEADACHE	2	01OCT2020	2/21	2	Yes		NA	R (21OCT2020)	N/N
>55/ C459100 1 1048 10481104	3^	GENRL	Fatigue/ FATIGUE	1	11SEP2020	3/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1048 10481105	3^	GENRL	Fatigue/ FATIGUE	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	30SEP2020	1/33	1	Yes		NA	R (01NOV2020)	N/N
		GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1048 10481117	3^	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1048 10481121	3^	GENRL	Injection site pain/ RIGHT ARM PAIN AT INJECTION SITE	1	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
		INV	Body temperature increased/ INCREASED TEMPERATURE 99.4 F	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ RIGHT ARM PAIN AT INJECTION SITE	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
>55/ C459100 1 1048 10481122	3^	MUSC	Back pain/ back pain	2	26OCT2020	28/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1048 10481123	3^	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1048 10481124	3^	INJ&P	Procedural pain/ MOUTH PAIN SECONDARY TO TOOTH EXTRACTION	2	18OCT2020	19/3	1	No	O	NA/TC	R (20OCT2020)	N/N
>55/ C459100 1 1048 10481129	3^	GENRL	Fatigue/ FATIGUE	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100 1 1054 10541021	3^	MUSC	Arthralgia/ worsening of right hip pain	1	24AUG2020	4/C	2	No	O	NA/TC/TCN	N	N/N
		GASTR	Abdominal discomfort/ abdominal discomfort	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
			Diarrhoea/ diarrhea	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1054 10541045	3^	GENRL	Nausea/ nausea	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
			Fatigue/ general tiredness	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
			Pyrexia/ fever	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1054 10541059	3^	MUSC	Myalgia/ muscle aches	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		GASTR	Gastrointestinal disorder/ colonic lesion	2	13OCT2020	30/1	1	No	O	NA	R (13OCT2020)	N/N
>55/ C459100 1 1054 10541062	3^	GENRL	Large intestine polyp/ colonic polyp	2	13OCT2020	30/1	1	No	O	NA	R (13OCT2020)	N/N
			Injection site pain/ injection site soreness	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N
>55/ C459100 1 1054 10541063	3^	GENRL	Pyrexia/ low grade fever of 99.4 degF	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N
			Chills/ chills	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1054 10541063	3^	GENRL	Injection site pain/ site injection pain	1	27AUG2020	1/2	1	Yes		NA/TC	R (28AUG2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ headache	1	27AUG2020	1/2	1	Yes		NA/TC	R (28AUG2020)	N/N
		GASTR	Nausea/ nausea	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ chills	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
			Pain/ body aches	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
			Pyrexia/ subjective fever	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ headache	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C459100 1 1054 10541075	3^	NERV	Dizziness/ intermittent dizziness	1	10SEP2020	14/2	2	No	O	NA	R (11SEP2020)	N/N
>55/ C459100 1 1054 10541077	3^	MUSC	Myalgia/ myalgia - generalized	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ headache	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Chills/ chills	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
			Pyrexia/ fever (99.6 degree F), subjective	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1054 10541093	3^	MUSC	Myalgia/ muscle soreness	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	02SEP2020	2/2	1	Yes		NA/TC	R (03SEP2020)	N/N
		NERV	Headache/ headache	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	03SEP2020	3/1	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ pain at injection site L arm	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
			Pain/ body aches	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1054 10541095	3^	NERV	Headache/ headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ pain L arm injection site	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y
>55/ C459100 1 1054 10541103	3^	GENRL	Injection site pain/ muscle soreness at injection site	1	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N
		NERV	Headache/ headache	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1054 10541112	3^	GENRL	Injection site pain/ muscle soreness R arm injection site	2	23SEP2020	1/3	1	Yes		NA/TC	R (25SEP2020)	N/N
		NERV	Headache/ headache	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Lethargy/ lethargy	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Dyskinesia/ LUE - mild involuntary movement of muscle	1	03SEP2020	1/1	1	Yes		NA	R (03SEP2020)	N/Y
		GASTR	Nausea/ nausea	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		INJ&P	Arthropod sting/ bee sting	1	19SEP2020	17/9	1	No	O	NA/TC	R (27SEP2020)	N/N
		VASC	Hot flush/ hot flash	1	21SEP2020	19/1	1	No	O	NA	R (21SEP2020)	N/N
		GASTR	Toothache/ toothache L lower tooth	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Sluggishness/ sluggish	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
NERV	Dizziness/ lightheadedness	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N		
			Headache/ headache	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1054 10541116	3^	GENRL	Asthenia/ generalized weakness	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		VASC	Hot flush/ hot flashes	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Muscle twitching/ intermittent migratory muscle twitches	2	26SEP2020	3/34	1	Yes		NA	R (29OCT2020)	N/N
		VASC	Hot flush/ hot flashes	2	26SEP2020	3/1	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Injection site pain/ soreness L arm injection site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ soreness at L arm injection site	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 1 1054 10541129	3^	MUSC	Myalgia/ generalized muscle aches	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site, L arm	1	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/Y
		GENRL	Fatigue/ fatigue	1	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		EYE	Vision blurred/ blurred vision	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Chills/ chills	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1054 10541134	3^	MUSC	Injection site pain/ injection site soreness	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Pyrexia/ fever	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Myalgia/ diffuse muscle aches	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ injection site soreness	2	30SEP2020	2/4	2	Yes		NA	R (03OCT2020)	N/N
		MUSC	Myalgia/ diffuse muscle aches	2	30SEP2020	2/4	2	Yes		NA/TC	R (03OCT2020)	N/N
		NERV	Headache/ headaches	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		PSYCH	Insomnia/ insomnia	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
			Paranoia/ paranoia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1054 10541136	3^	GENRL	Injection site pain/ injection site muscle ache	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1054 10541136	3^	INV	Blood pressure increased/ elevated blood pressure	1	09SEP2020	1/2	1	No	O	NA	R (10SEP2020)	N/N
		NERV	Dizziness/ lightheadedness	1	09SEP2020	1/1	1	No	O	NA	R (09SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1054 10541149	3^	GASTR	Dyspepsia/ intermittent heartburn	1	30SEP2020	20/C	1	No	O	NA/TC	N	N/N
		GASTR	Tongue discolouration/ black discoloration of tongue	2	05OCT2020	4/26	1	No	CD	NA	R (30OCT2020)	N/N
>55/ C459100 1 1054 10541151	3^	GENRL	Injection site pain/ pain at injection site	1	15SEP2020	2/3	1	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Injection site pain/ soreness L arm injection site	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		GENRL	Chills/ chills	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
			Injection site pain/ soreness L arm injection site	2	06OCT2020	2/4	2	Yes		NA/TC	R (09OCT2020)	N/N
			Injection site swelling/ swelling L arm injection site	2	06OCT2020	2/12	1	Yes		NA	R (17OCT2020)	N/N
			Pain/ body aches	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
			Pyrexia/ fever	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
		NERV	Headache/ headache	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
		2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N		
>55/ C459100	3^	NERV	Dizziness/ lightheadedness	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1054 10541163	3^	GENRL	Injection site pain/ muscle pain L arm injection site	1	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
1 1054 10541164	3^	GENRL	Injection site pain/ soreness at R arm injection site	1	17SEP2020	1/5	1	Yes		NA	R (21SEP2020)	N/N
			Injection site swelling/ swelling at R arm injection site	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ chills	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
			Injection site pain/ pain at injection site	2	08OCT2020	1/6	1	Yes		NA/TC	R (13OCT2020)	N/N
			Pyrexia/ fever - 101 degrees Fahrenheit	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		SKIN	Hyperhidrosis/ diaphoresis (mild)	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1054 10541169	3^	GASTR	Nausea/ nausea	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/Y
		GENRL	Injection site pain/ injection site pain	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ burning at L arm injection site	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1054 10541173	3^	CARD	Non-cardiac chest pain/ L chest discomfort (noncardiac)	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/Y
			Aortic valve incompetence/ acute severe aortic insufficiency	2	28OCT2020	20/C	4	No	O	NA/TC/TCN	N	Y/N
			Endocarditis bacterial/ bacterial endocarditis	2	28OCT2020	20/C	2	No	O	NA/TC	RG	N/N
			Myalgia/ pain L hamstring muscles	2	28OCT2020	20/C	2	No	O	NA/TC	N	N/N
			Subarachnoid haemorrhage/ subarachnoid hemorrhage	2	05NOV2020	28/C	3	No	O	NA/TC/TCN	N	Y/N
>55/ C459100 1 1054 10541186	3^	GASTR	Atrial fibrillation/ intermittent atrial fibrillation	2	06NOV2020	29/C	2	No	O	NA/TC	RG	N/N
			Nausea/ nausea	1	23SEP2020	1/1	1	Yes		P	R (23SEP2020)	N/Y
>55/ C459100 1 1054 10541187	3^	GASTR	Dizziness/ lightheadedness	1	23SEP2020	1/1	1	Yes		P	R (23SEP2020)	N/Y
			Abdominal pain upper/ intermittent upper abdominal pain	2	15OCT2020	2/3	1	Yes		NA	R (17OCT2020)	N/N
			Nausea/ nausea	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
			GENRL	Chills/ chills	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Fatigue/ tiredness	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
			Pyrexia/ fever	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		MUSC	Myalgia/ muscle aches	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
		NERV	Headache/ headache	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1055 10551006	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	2	01SEP2020	7/6	1	No	O	NA/TC	R (06SEP2020)	N/N
>55/ C459100 1 1055 10551011	3^	EAR	Vertigo positional/ Worsening of recurrent benign positional vertigo	2	07SEP2020	8/36	3	No	O	NA/TC	R (12OCT2020)	N/N
>55/ C459100 1 1055 10551018	3^	EYE	Retinal detachment/ Detached retina	2	10SEP2020	11/8	3	No	O	NA/TC/TCN	R (17SEP2020)	N/N
>55/ C459100 1 1055 10551024	3^	NEOPL	Basal cell carcinoma/ Basal cell cancer	1	11AUG2020	1/81	2	No	O	NA	R (30OCT2020)	N/N
>55/ C459100 1 1055 10551039	3^	GASTR	Hypoaesthesia oral/ Tongue numbness	1	13AUG2020	1/1	1	Yes		NA/TC	R (13AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Asthma/ Asthma exacerbation	1	19AUG2020	7/35	2	No	O	NA/TC	R (22SEP2020)	N/N
>55/ C459100 1 1055 10551052	3^	GENRL	Injection site pain/ Injection site tenderness	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
>55/ C459100 1 1055 10551055	3^	IMMUN	Seasonal allergy/ Seasonal Allergies	2	29SEP2020	22/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1055 10551059	3^	GENRL	Injection site pain/ Injection site pain	1	17AUG2020	1/4	1	Yes		NA	R (20AUG2020)	N/N
		GASTR	Nausea/ Nausea	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pruritus/ Injection site itching	2	10SEP2020	2/15	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1055 10551060	3^	GENRL	Injection site pain/ Injection site pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
>55/ C459100 1 1055 10551064	3^	GENRL	Injection site pain/ Left arm injection site pain	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1055 10551068	3^	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
		GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1055 10551081	3^		Fatigue/ Fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
>55/ C459100 1 1055 10551083	3^	GENRL	Fatigue/ Fatigue	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	11SEP2020	2/4	2	Yes		NA	R (14SEP2020)	N/N
			Pyrexia/ Fever	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
		NERV	Headache/ Headache	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1055 10551091	3^	RENAL	Bladder spasm/ Bladder spasm	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	24AUG2020	1/4	2	Yes		NA	R (27AUG2020)	N/N
		EAR	Vertigo/ Vertigo	1	26AUG2020	3/5	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	14SEP2020	1/4	1	Yes		NA	R (17SEP2020)	N/N
		EAR	Vertigo/ Vertigo	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Chills/ Chills	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1055 10551093	3^	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	2/1	2	Yes		NA/TC	R (25AUG2020)	N/N
		MUSC	Myalgia/ Myalgia	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1055 10551094	3^	MUSC	Arthralgia/ Arthralgia generalized	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1055 10551095	3^	NERV	Headache/ Headache	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1055 10551096	3^	NERV	Headache/ Headache	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	25AUG2020	2/5	2	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 1 1055 10551100	3^	GENRL	Chills/ Chills	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	15SEP2020	2/3	1	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	17SEP2020	4/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	2/5	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1055 10551102	3^	MUSC	Myalgia/ Myalgias	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1055 10551106	3^	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	2/2	2	Yes		NA/TC	R (27AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C459100 1 1055 10551107	3^	GENRL	Injection site pain/ Injection Site Pain	1	26AUG2020	2/4	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1055 10551110	3^	PSYCH	Nightmare/ Nightmares	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		GASTR	Nausea/ Nausea	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
		GASTR	Nausea/ Nausea	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1055 10551112	3^	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		PSYCH	Insomnia/ Insomnia	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/N
			Injection site pain/ Injection site pain	1	25AUG2020	1/5	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 1 1055 10551113	3^	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1055 10551114	3^	GENRL	Chills/ Chills	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
			Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
		GASTR	Nausea/ Nausea	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
>55/ C459100	3^	GASTR	Nausea/ Nausea	2	18SEP2020	3/1	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1055 10551119		GENRL	Chills/ Chills	1	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N
			Fatigue/ Fatigue	1	27AUG2020	2/1	2	Yes		NA	R (27AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	16SEP2020	1/6	2	Yes		NA	R (21SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
			Fatigue/ Fatigue	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1055 10551122	3^	MUSC	Arthritis/ Arthritis of hands	2	28SEP2020	12/C	1	No	O	NA	N	N/N
>55/ C459100 1 1055 10551124	3^	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
>55/ C459100 1 1055 10551126	3^	GENRL	Injection site pain/ Injection Site Pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1055 10551127	3^	GENRL	Injection site pain/ Injection Site Pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
>55/ C459100 1 1055 10551132	3^	GENRL	Injection site pain/ Left arm injection site tenderness	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C459100 1 1055 10551137	3^	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 1 1055 10551140	3^	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
			Injection site pain/ Injection site pain	1	28AUG2020	1/8	1	Yes		NA	R (04SEP2020)	N/N
			Injection site pruritus/ Injection site itching	1	28AUG2020	1/8	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	16SEP2020	1/6	2	Yes		NA	R (21SEP2020)	N/N
			Injection site swelling/ Injection Site Swelling	2	16SEP2020	1/6	2	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1055 10551147	3^	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		NERV	Headache/ Headache	1	31AUG2020	1/2	1	Yes		NA/TC	R (01SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1055 10551148	3^	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1055 10551150	3^	GENRL	Injection site pain/ Injection site pain	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1055 10551153	3^	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1055 10551155	3^	INFEC	Appendicitis perforated/ Perforated appendicitis	1	31AUG2020	1/17	3	No	O	NA/TC/TCN	R (16SEP2020)	Y/N
		GENRL	Fatigue/ Fatigue	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
		GASTR	Food poisoning/ Food poisoning	1	20SEP2020	21/2	1	No	O	NA	R (21SEP2020)	N/N
>55/ C459100 1 1055 10551158	3^	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Injection site pain/ Left injection site pain	1	01SEP2020	1/6	1	Yes		NA/TC	R (06SEP2020)	N/N
		GENRL	Injection site erythema/ Left injection site erythema	1	02SEP2020	2/5	1	Yes		NA	R (06SEP2020)	N/N
>55/ C459100 1 1055 10551159	3^	GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/15	2	Yes		NA/TC	R (06OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site left arm	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	24SEP2020	3/3	1	Yes		NA/TC	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1055 10551167	3^	GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1055 10551170	3^	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		REPRO	Prostatitis/ Prostatitis	2	19OCT2020	27/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1055 10551178	3^	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	05SEP2020	3/1	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Chills/ Chills	1	05SEP2020	3/1	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	1/2	1	Yes		NA/TCN	R (24SEP2020)	N/N
		GENRL	Chills/ Chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100	3^	NEOPL	Basal cell carcinoma/ Basal Cell Cancer	1	25SEP2020	23/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1055 10551182	3^	GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/3	2	Yes		NA/TC	R (06SEP2020)	N/N
1 1055 10551189		GENRL	Injection site pain/ Injection site pain	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C459100 1 1055 10551189	3^	GASTR	Nausea/ Nausea	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	1/4	2	Yes		NA/TC	R (27SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	25SEP2020	2/3	2	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C459100 1 1055 10551194	3^	GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/3	2	Yes		NA	R (06SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	1/4	2	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1055 10551197	3^	CARD	Tachycardia/ Tachycardia	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Chills/ Chills	2	24SEP2020	2/1	3	Yes		NA	R (24SEP2020)	N/N
			Malaise/ Malaise	2	24SEP2020	2/3	3	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1055 10551201	3^	GENRL	Injection site pain/ Injection site pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		INJ&P	Corneal abrasion/ Corneal abrasion	1	24SEP2020	17/6	2	No	O	NA/TC/TCN	R (29SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	29SEP2020	1/45	2	Yes		NA	R (12NOV2020)	N/N
		GENRL	Fatigue/ Fatigue	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Injection site pain/ Injection Site Pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
		Pyrexia/ Fever	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1055 10551205	3^	MUSC	Myalgia/ Generalized myalgias	1	11SEP2020	3/1	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ Headache	1	11SEP2020	3/1	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	04OCT2020	5/3	1	Yes		NA	R (06OCT2020)	N/N
		NERV	Headache/ Headache	2	04OCT2020	5/3	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1055 10551212	3^	GENRL	Injection site pain/ Pain at injection site	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
			Malaise/ Malaise	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	2/6	1	Yes		NA/TC	R (06OCT2020)	N/N
>55/ C459100 1 1055 10551214	3^	GENRL	Injection site pain/ Injection site pain	1	13SEP2020	4/3	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Myalgias	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
		NERV	Headache/ Headache	2	01OCT2020	2/1	2	Yes		NA/TC	R (01OCT2020)	N/N
		BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	2	18OCT2020	19/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1055 10551217	3^	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C459100 1 1055 10551218	3^	GENRL	Fatigue/ Fatigue	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	2/15	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1055 10551236	3^	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	1/5	2	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/ Injection site pain	2	05OCT2020	1/5	2	Yes		NA/TC	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Myalgias	2	05OCT2020	1/3	2	Yes		NA/TC	R (07OCT2020)	N/N
		SKIN	Night sweats/ Night sweats	2	07OCT2020	3/1	2	Yes		NA	R (07OCT2020)	N/N
>55/ C459100 1 1056 10561030	3^	GENRL	Pyrexia/ FEVER	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1056 10561040	3^	GENRL	Pyrexia/ FEVER	2	29OCT2020	46/4	1	No	O	NA	R (01NOV2020)	N/N
		MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	2	29OCT2020	46/4	1	No	O	NA	R (01NOV2020)	N/N
		NERV	Headache/ HEADACHE	2	29OCT2020	46/4	1	No	O	NA	R (01NOV2020)	N/N
>55/ C459100 1 1056 10561064	3^	GENRL	Injection site pain/ PAIN IN INJECTION SITE	1	30AUG2020	4/4	1	Yes		NA	R (02SEP2020)	N/N
>55/ C459100 1 1056 10561083	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE LEFT	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
>55/ C459100 1 1056 10561086	3^	GENRL	Injection site pain/ TENDERNESS AT INJECTION SITE	1	30AUG2020	2/5	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1056 10561120	3^	EAR	Tinnitus/ HEARS A NOISE IN HIS RIGHT EAR	1		1/						/N
>55/ C459100 1 1056 10561180	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE MUSCLE PAIN	2	28SEP2020	1/4	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 1 1056 10561257	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1056 10561324	3^	GENRL	Pyrexia/ FEVER	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C459100 1 1056 10561362	3^	INFEC	Rhinitis/ RHINITIS	1	07OCT2020	9/4	1	No	O	NA	R (10OCT2020)	N/N
>55/ C459100 1 1056 10561416	3^	EAR	Vertigo/ VERTIGO	1	07OCT2020	2/6	1	No	O	NA	R (12OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	26OCT2020	1/6	1	Yes		NA	R (31OCT2020)	N/N
		PSYCH	Anxiety/ ACUTE ANXIETY ATTACK	2	09NOV2020	15/1	1	No	O	NA	R (09NOV2020)	N/N
>55/ C459100	3^	GASTR	Stomatitis/ ORAL STOMATITIS	1	11OCT2020	4/4	1	No	O	NA	R (14OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1056 10561449 >55/ C459100	3^	GASTR	Diarrhoea/ DIARRHEA	2	28OCT2020	1/9	1	Yes		NA	R (05NOV2020)	N/N
1 1056 10561454		NERV	Headache/ HEADACHE	2	28OCT2020	1/9	1	Yes		NA	R (05NOV2020)	N/N
>55/ C459100 1 1057 10571004	3^	GENRL	Chills/ Chills	2	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
			Injection site pain/ Injection Site Soreness	2	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
			Pain/ Body Aches	2	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
			Pyrexia/ Fever	2	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		SKIN	Rash/ RASH ON TRUNK	2	29SEP2020	30/33	1	Yes		NA	R (31OCT2020)	N/N
>55/ C459100 1 1057 10571052	3^	INFEC	Pneumonia/ PNEUMONIA	2	20SEP2020	12/15	2	No	O	NA/TC	R (04OCT2020)	Y/N
>55/ C459100 1 1057 10571107	3^	GASTR	Diarrhoea/ DIARRHEA	2	17SEP2020	3/2	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1057 10571133	3^	SKIN	Skin mass/ ENLARGEMENT OF SUBCUTANEOUS MASS OVER RIGHT SHOULDER BLADE	2	01OCT2020	11/C	1	No	O	NA	N	N/N
>55/ C459100 1 1057 10571150	3^	GENRL	Chills/ CHILLS	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
			Fatigue/ FATIGUE	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
			Injection site pain/ PAIN AT INJECTION SITE	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 1 1057 10571181	3^	GENRL	Pyrexia/ Fever	1	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1057 10571190	3^	GASTR	Diarrhoea/ LOOSE STOOLS	1	16SEP2020	2/4	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Sluggishness/ SLUGGISHNESS	1	16SEP2020	2/4	1	Yes		NA	R (19SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	1	16SEP2020	2/4	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1057 10571290	3^	GENRL	Chills/ Chills	2	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1066 10661005	3^	RESP	Cough/ dry cough due to air quality	1	30AUG2020	20/2	1	No	O	NA	R (31AUG2020)	N/N
>55/ C459100 1 1066 10661007	3^	GENRL	Fatigue/ Fatigue	1	11AUG2020	1/23	1	Yes		NA	R (02SEP2020)	N/N
>55/ C459100 1 1066 10661009	3^	GENRL	Fatigue/ fatigue	1	12AUG2020	1/3	1	Yes		NA	R (14AUG2020)	N/N
			Injection site pain/ injection site pain	1	12AUG2020	1/4	1	Yes		NA	R (15AUG2020)	N/N
		GENRL	Injection site erythema/ injection site redness	1	13AUG2020	2/2	1	Yes		NA	R (14AUG2020)	N/N
>55/ C459100 1 1066 10661012	3^	GENRL	Injection site pain/ Injection site pain	1	13AUG2020	2/2	1	Yes		NA	R (14AUG2020)	N/N
		GASTR	Diarrhoea/ diarrhea	1	16AUG2020	5/2	1	Yes		NA	R (17AUG2020)	N/N
		GENRL	Fatigue/ fatigue	1	16AUG2020	5/2	1	Yes		NA	R (17AUG2020)	N/N
		NERV	Headache/ headache	1	18AUG2020	7/2	1	Yes		NA	R (19AUG2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ injection site pain	1	13AUG2020	2/2	1	Yes		NA	R (14AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1066 10661016 >55/ C459100	3^	NERV	Migraine/ migraine	2	06OCT2020	28/2	2	No	O	NA/TC	R (07OCT2020)	N/N
1 1066 10661046 >55/ C459100	3^	NERV	Dizziness/ dizziness	1	22AUG2020	3/2	1	Yes		NA	R (23AUG2020)	N/N
1 1066 10661066		RESP	Epistaxis/ epistaxis	1	22AUG2020	3/2	1	Yes		NA	R (23AUG2020)	N/N
		GASTR	Vomiting/ vomiting	1	23AUG2020	4/2	1	Yes		NA	R (24AUG2020)	N/N
		GENRL	Fatigue/ fatigue	1	23AUG2020	4/2	1	Yes		NA	R (24AUG2020)	N/N
		INFEC	Ear infection/ ear infection	1	22SEP2020	34/6	1	No	O	NA/TC	R (27SEP2020)	N/N
>55/ C459100 1 1066 10661074	3^	GENRL	Fatigue/ fatigue	1	21AUG2020	2/7	1	Yes		NA	R (27AUG2020)	N/N
			Pain/ body aches	1	21AUG2020	2/7	1	Yes		NA	R (27AUG2020)	N/N
		NERV	Headache/ headache	1	21AUG2020	2/7	1	Yes		NA	R (27AUG2020)	N/N
>55/ C459100	3^	NERV	Dizziness/ dizziness	2	24SEP2020	16/2	1	No	O	NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1066 10661080 >55/ C459100 1 1066 10661091	3^	NERV	Dizziness/ dizziness	1	27AUG2020	3/2	1	Yes		NA	R (28AUG2020)	N/N
1 1066 10661091 >55/ C459100 1 1066 10661109	3^	NERV	Dizziness/ dizziness	2	19SEP2020	2/2	1	No	O	NA	R (20SEP2020)	N/N
1 1066 10661109 >55/ C459100 1 1066 10661114	3^	GENRL	Injection site pain/ injection site pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
1 1066 10661114 >55/ C459100 1 1066 10661128	3^	MUSC	Bursitis/ bursitis left knee	1	03SEP2020	9/7	1	No	O	NA/TC	R (09SEP2020)	N/N
1 1066 10661128 >55/ C459100 1 1066 10661134	3^	MUSC	Arthralgia/ right shoulder pain	1	01SEP2020	6/C	1	No	O	NA	N	N/N
1 1066 10661134 >55/ C459100 1 1066 10661134	3^	NERV	Headache/ intermittent headaches	1	01SEP2020	6/C	1	No	O	NA	N	N/N
1 1066 10661134 >55/ C459100 1 1066 10661134	3^	INFEC	Localised infection/ infected right index finger	2	10OCT2020	24/C	1	No	O	NA/TC	RG	N/N
1 1066 10661134 >55/ C459100	3^	GENRL	Pain/ body aches	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1066 10661153			Pyrexia/ fever	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1066 10661175	3^	GENRL	Chills/ chills	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
			Pain/ body aches	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1066 10661227	3^	GENRL	Injection site pain/ pain at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 1 1066 10661231	3^	GENRL	Injection site erythema/ redness at injection site	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1066 10661234	3^	GENRL	Chills/ chills	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
			Fatigue/ fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1066 10661240	3^	GENRL	Pain/ body aches	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1066 10661255	3^	GENRL	Pyrexia/ fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
			Pain/ body aches	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1066 10661292	3^	GENRL	Pain/ body aches	2	15OCT2020	2/4	1	Yes		NA	R (18OCT2020)	N/N
>55/ C459100 1 1066 10661298	3^	SKIN	Hyperhidrosis/ sweating	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1066 10661303	3^	GENRL	Pain/ body aches	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
			Pyrexia/ fever	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1068 10681004	3^	NERV	Headache/ headache	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	1	19AUG2020	1/4	1	Yes		NA/TC/TCN	R (22AUG2020)	N/N
			Pyrexia/ Fever	1	19AUG2020	1/2	1	Yes		NA/TC/TCN	R (20AUG2020)	N/N
		NERV	Headache/ Headache	1	19AUG2020	1/4	1	Yes		NA/TC/TCN	R (22AUG2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	2	09SEP2020	1/6	1	Yes		NA/TC	R (14SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	10SEP2020	2/3	1	Yes		NA/TC/TCN	R (12SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
>55/ C459100 1 1068 10681008	3^	NERV	Headache/ Headache	2	10SEP2020	2/3	1	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/2	1	Yes		NA/TC	R (20AUG2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Aches	1	20AUG2020	2/1	1	Yes		NA/TC/TCN	R (20AUG2020)	N/N
		GENRL	Chills/ Chills	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)			
			Injection site pain/ Injection site pain	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N			
			Pyrexia/ Fever	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N			
			MUSC Myalgia/ Muscle Aches	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N			
			NERV Headache/ Headache	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N			
>55/ C459100 1 1068 10681009	3^	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/2	1	Yes		NA/TC	R (20AUG2020)	N/N			
			MUSC Myalgia/ Muscle Aches	1	20AUG2020	2/1	1	Yes		NA/TC	R (20AUG2020)	N/N			
			>55/ C459100 1 1068 10681019	3^	GENRL	Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			GENRL Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N			
			Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N			
			NERV Headache/ Headache	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N			
			>55/ C459100 1 1068 10681020	3^	MUSC	Myalgia/ Myalgia	1	23AUG2020	3/5	1	Yes		NA/TC	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1068 10681023	3^	GENRL	Injection site pain/ Pain at injection site	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
		SKIN	Rash/ Rash on legs	1	24AUG2020	4/2	1	Yes		NA	R (25AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		SKIN	Rash/ Rash on arms and trunk	2	13SEP2020	3/3	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1068 10681030	3^	MUSC	Myalgia/ generalized muscle pain	1	24AUG2020	1/4	1	Yes		NA	R (27AUG2020)	N/N
>55/ C459100 1 1068 10681033	3^	SKIN	Skin induration/ Firm swelling induration on left arm	1	29AUG2020	6/C	1	Yes		NA	RG	N/N
>55/ C459100 1 1068 10681041	3^	GENRL	Fatigue/ Fatigue	1	26AUG2020	1/3	2	Yes		NA	R (28AUG2020)	N/N
			Injection site pain/ Injection site pain	1	26AUG2020	1/3	2	Yes		NA	R (28AUG2020)	N/N
		NERV	Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		RESP	Asthma/ Asthma exacerbation	1	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Arthralgia/ Joint pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Fatigue/ Fatigue	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Pyrexia/ Fever	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		MUSC	Arthralgia/ Joint Aches	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
			Myalgia/ Muscle Aches	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1068 10681045	3^	INJ&P	Respiratory fume inhalation disorder/ cough from wildfire smoke per provider and air quality index	1	13SEP2020	19/6	1	No	O	NA	R (18SEP2020)	N/N
>55/ C459100 1 1068 10681050	3^	GENRL	Pyrexia/ Fever	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N
		MUSC	Pain in extremity/ Sore left arm	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Chills/ Chills	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ Fever	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1068 10681056	3^	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	29AUG2020	3/1	1	No	O	NA	R (29AUG2020)	N/N
		GENRL	Chills/ Chills	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1068 10681057	3^	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/5	1	Yes		NA/TC/TCN	R (31AUG2020)	N/N
>55/ C459100 1 1068 10681059	3^	GENRL	Injection site erythema/ Redness at injection site (2 inch diameter)	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
			Injection site pain/ Injection Site Pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 1 1068 10681062	3^	INV	Glomerular filtration rate decreased/ Decreased GFR	1	03SEP2020	7/C	1	No	O	NA	N	N/N
>55/ C459100	3^	ENDO	Hypothyroidism/ hypothyroidism	2	09OCT2020	19/C	2	No	O	NA/TC	N	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1068 10681075	3^	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/6	1	Yes		NA	R (05SEP2020)	N/N
1 1068 10681078		MUSC	Myalgia/ Muscle Pain Left Back	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ Chills	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1068 10681079	3^	MUSC	Myalgia/ Muscle aches	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1068 10681082	3^	GENRL	Fatigue/ Fatigue	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		NERV	Headache/ Head Ache	1	31AUG2020	1/2	1	Yes		NA/TC/TCN	R (01SEP2020)	N/Y
		MUSC	Arthralgia/ Left shoulder pain	1	01SEP2020	2/1	1	No	O	NA/TC/TCN	R (01SEP2020)	N/N
			Neck pain/ Left neck pain	1	01SEP2020	2/7	1	No	O	NA/TC/TCN	R (07SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1068 10681084		NERV	Headache/ Headache	1	01SEP2020	1/3	1	Yes		NA/TC	R (03SEP2020)	N/N
>55/ C459100 1 1068 10681088	3^	GENRL	Injection site pain/ Pain at injection site	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
>55/ C459100 1 1068 10681090	3^	GENRL	Injection site pain/ Pain at the injection site	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
		NERV	Headache/ Headache	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1068 10681092	3^	INV	Emergency care examination/ ED visit nephrolithiasis	1	04SEP2020	3/1	2	No	O	NA/TC	R (04SEP2020)	N/N
>55/ C459100 1 1068 10681095	3^	GENRL	Injection site pain/ Pain at the injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/Y
		GENRL	Vessel puncture site bruise/ Bruising of arm from blood draw	1	03SEP2020	2/8	1	No	O	NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1068 10681096	3^	GENRL	Fatigue/ fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ Mynlgia	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1068 10681104	3^	NERV	Headache/ Headache	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	25SEP2020	1/7	1	Yes		NA	R (01OCT2020)	N/N
			Nausea/ Nausea	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		GENRL	Chills/ Chills	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N
			Fatigue/ Fatigue	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ Headache	2	28SEP2020	4/22	1	Yes		NA/TC	R (19OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1068 10681111	3^	BLOOD	Lymphadenopathy/ Swollen Cervical Lymph Nodes bilateral	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
		RESP	Rhinorrhoea/ Rhinorrhea	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
			Sneezing/ Sneezing	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
>55/ C459100 1 1068 10681118	3^	GENRL	Chills/ Chills	1	10SEP2020	1/5	1	Yes		NA	R (14SEP2020)	N/N
		NERV	Headache/ Headache	1	10SEP2020	1/5	1	Yes		NA/TC	R (14SEP2020)	N/N
		NERV	Headache/ Mild Headache	2	30SEP2020	1/3	1	Yes		NA/TC	R (02OCT2020)	N/N
		GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1068 10681122	3^	GENRL	Fatigue/ Fatigue	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
			Injection site pain/ Injection Site Pain	1	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1071 10711023	3^	CARD	Coronary artery disease/ WORSENING coronary artery disease	1	23AUG2020	12/C	2	No	O	P/TCN/W	N	Y/N
>55/ C459100 1 1071 10711033	3^	GENRL	Fatigue/ FATIGUE	1	18AUG2020	6/15	2	No	O	NA	R (01SEP2020)	N/N
>55/ C459100 1 1071 10711035	3^	GENRL	Injection site bruising/ SMALL BRUISE AT INJECTION SITE	1	13AUG2020	1/2	1	Yes		NA	R (14AUG2020)	N/N
		MUSC	Limb discomfort/ LEG DISCOMFORT	2	09SEP2020	9/3	1	No	O	NA	R (11SEP2020)	N/N
>55/ C459100 1 1071 10711051	3^	NERV	Tremor/ LEFT ARM TREMOR	1	30AUG2020	14/1	1	No	O	NA	R (30AUG2020)	N/N
>55/ C459100 1 1071 10711052	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
>55/ C459100 1 1071 10711053	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
			Injection site swelling/ SWELLING AT INJECTION SITE	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1071 10711060	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 1 1071 10711067	3^	MUSC	Musculoskeletal stiffness/ MUSCLE STIFFNESS	1	07SEP2020	20/3	1	No	O	NA	R (09SEP2020)	N/N
>55/ C459100 1 1071 10711069	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
>55/ C459100 1 1071 10711070	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	1/3	2	Yes		NA	R (22AUG2020)	N/N
>55/ C459100 1 1071 10711071	3^	RESP	Rhinorrhoea/ INTERMITTENT RUNNY NOSE	1	20AUG2020	1/21	1	No	O	NA	R (09SEP2020)	N/N
>55/ C459100 1 1071 10711076	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1071 10711077	3^	GENRL	Injection site bruising/ INJECTION SITE BRUISING	1	22AUG2020	2/26	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1071 10711078	3^	MUSC	Arthralgia/ JOINT PAIN IN KNEES	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
>55/ C459100 1 1071 10711084	3^	GENRL	Fatigue/ FATIGUE	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
			Injection site erythema/ REDNESS AT INJECTION SITE	2	14SEP2020	1/12	2	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1071 10711088	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
		INFEC	Injection site abscess/ ABSCESS AROUND INJECTION SITE LEFT ARM	2	21SEP2020	7/24	2	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 1071 10711112	3^	GASTR	Diarrhoea/ DIARRHEA	1	13SEP2020	17/1	1	No	O	NA	R (13SEP2020)	N/N
>55/ C459100 1 1071 10711120	3^	INJ&P	Arthropod bite/ INSECT BITES	1	16SEP2020	15/15	1	No	O	NA	R (30SEP2020)	N/N
		GENRL	Pyrexia/ FEVER	1	18SEP2020	17/2	1	No	O	NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1071 10711121	3^	GENRL	Chills/ CHILLS	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1071 10711126	3^	RESP	Nasal congestion/ NASAL CONGESTION	1	21SEP2020	19/2	1	No	O	NA	R (22SEP2020)	N/N
			Wheezing/ WHEEZING	1	21SEP2020	19/2	1	No	O	NA	R (22SEP2020)	N/N
>55/ C459100 1 1071 10711134	3^	GASTR	Vomiting/ VOMITING	2	10OCT2020	16/1	1	No	O	NA	R (10OCT2020)	N/N
>55/ C459100 1 1071 10711139	3^	GASTR	Nausea/ NAUSEA	1	19SEP2020	12/2	1	No	O	NA	R (20SEP2020)	N/N
		RESP	Cough/ COUGH	1	19SEP2020	12/2	1	No	O	NA	R (20SEP2020)	N/N
>55/ C459100 1 1071 10711144	3^	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ PAIN AT INJECTION SITE	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Injection site swelling/ SWELLING AT INJECTION SITE	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1071 10711169	3^	INJ&P	Alcohol poisoning/ ACUTE ALCOHOL INTOXICATION	1	02OCT2020	18/14	2	No	O	P/W	R (15OCT2020)	Y/N
>55/ C459100 1 1071 10711178	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
			Pyrexia/ FEVER	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		GENRL	Injection site swelling/ SWELLING ST INJECTION SITE	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C459100 1 1071 10711180	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1071 10711181	3^	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Injection site pain/ PAIN AT THE INJECTION SITE	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1071 10711207	3^	GENRL	Pyrexia/ LOW GRADE FEVER	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1072 10721005	3^	GASTR	Tongue pruritus/ Sides of tongue itching	2	08SEP2020	1/1	1	Yes		NA/TC	R (08SEP2020)	N/Y
>55/ C459100 1 1072 10721007	3^	NERV	Transient ischaemic attack/ Transient Ischaemic Attack	1	04SEP2020	19/6	2	No	O	NA/TC/TCN	R (09SEP2020)	Y/N
>55/ C459100 1 1072 10721014	3^	INJ&P	Burn oral cavity/ Burn in mouth	1	06SEP2020	19/6	1	No	O	NA/TC	R (11SEP2020)	N/N
>55/ C459100 1 1072 10721018	3^	NERV	Dizziness/ DIZZINESS	2	06OCT2020	28/2	1	No	O	NA	R (07OCT2020)	N/N
>55/ C459100 1 1077 10771006	3^	INJ&P	Fall/ FALL	1	27AUG2020	18/1	2	No	O	NA	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1077 10771039	3^	PSYCH	Rib fracture/ TWO FRACTURED RIBS	1	27AUG2020	18/75	2	No	O	NA/TC	R (09NOV2020)	N/N
>55/ C459100 1 1077 10771039	3^	PSYCH	Anxiety/ WORSENING ANXIETY	1	20AUG2020	9/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1077 10771047	3^	INFEC	Acute sinusitis/ ACUTE SINUSITIS	2	25SEP2020	18/14	2	No	O	NA/TC	R (08OCT2020)	N/N
>55/ C459100 1 1077 10771049	3^	NERV	Facial paralysis/ BELL'S PALSY	2	25OCT2020	48/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1077 10771064	3^	INJ&P	Skin abrasion/ RIGHT FOREARM ABRASIONS	2	16SEP2020	8/3	1	No	O	NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1077 10771090	3^	NERV	Neuralgia/ ACUTE NEURALGIA	2	17OCT2020	34/C	1	No	O	NA	N	N/N
>55/ C459100 1 1077 10771099	3^	VASC	Hot flush/ INTERMITTENT HOT FLASHES	1	25AUG2020	1/C	1	No	O	NA	N	N/N
>55/ C459100 1 1077 10771111	3^	INJ&P	Wound/ PUNCTURE WOUNDS, BILATERAL HANDS	1	25AUG2020	1/11	2	No	O	NA/TC	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1077 10771112	3^	RENAL	Nephrolithiasis/ KIDNEY STONES, RIGHT KIDNEY	2	18OCT2020	33/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1077 10771164	3^	INJ&P	Animal bite/ DOG BITE	1	16SEP2020	15/1	1	No	O	NA/TC	R (16SEP2020)	N/N
			Skin abrasion/ RIGHT FOREARM ABRASIONS	1	16SEP2020	15/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1077 10771179	3^	MUSC	Muscle spasms/ WORSENING BACK SPASMS	2	07OCT2020	16/C	1	No	O	NA	N	N/N
>55/ C459100 1 1077 10771180	3^	IMMUN	Seasonal allergy/ WORSENING SEASONAL ALLERGIES	2	29SEP2020	8/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1077 10771194	3^	GASTR	Aphthous ulcer/ RECURRENT ORAL APTHAE	1	12SEP2020	9/C	1	No	O	NA/TC	N	N/N
			Stomatitis/ ORAL MUCOSITIS	1	12SEP2020	9/C	1	No	O	NA/TC	N	N/N
		INFECTION	Cellulitis/ CELLULITIS RIGHT 5TH FINGER	2	08OCT2020	14/12	1	No	O	NA/TC	R (19OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1077 10771205	3^	SKIN	Urticaria/ URTICARTIA, LEFT DELTOID	2	25OCT2020	28/6	1	No	O	NA	R (30OCT2020)	N/N
>55/ C459100 1 1077 10771223	3^	EAR	Vertigo/ VERTIGO	2	01OCT2020	2/34	1	Yes		NA/TC	R (03NOV2020)	N/N
		MUSC	Spinal osteoarthritis/ WORSENING OSTEOARTHRITIS, NECK	2	10OCT2020	11/32	2	No	O	NA/TC	R (10NOV2020)	N/N
>55/ C459100 1 1079 10791020	3^	INJ&P	Fall/ Fall (patient tripped over shoe and hit the ground)*		31JUL2020	1/1	1	No	O	NA	R (31JUL2020)	N/N
>55/ C459100 1 1079 10791078	3^	INFEC	Skin bacterial infection/ BACTERIAL SKIN INFECTION RIGHT BREAST	1	17AUG2020	11/12	1	No	O	NA/TC/TCN	R (28AUG2020)	N/N
>55/ C459100 1 1079 10791111	3^	RESP	Chronic obstructive pulmonary disease/ COPD Exacerbation	1	19AUG2020	8/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1079 10791228	3^	EYE	Retinal artery occlusion/ Central Retinal Artery Occlusion	2	29SEP2020	1/C	1	No	O	NA	N	Y/N
>55/ C459100	3^	NERV	Aphasia/ Expressive Aphasia	2	22OCT2020	28/5	2	No	O	NA	R (26OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1079 10791246			Cerebrovascular accident/ CVA	2	22OCT2020	28/5	2	No	O	NA	R (26OCT2020)	Y/N
>55/ C459100 1 1079 10791264	3^	MUSC	Back pain/ Worsening of Low Back Pain	1	27SEP2020	19/5	2	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1080 10801006	3^	GASTR	Nausea/ Nausea	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y
		GENRL	Injection site erythema/ Redness at injection site	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y
		GENRL	Injection site swelling/ Swelling at injection site	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y
		GASTR	Diarrhoea/ Intermittent Diarrhea	1	12AUG2020	3/8	1	No	O	NA	R (19AUG2020)	N/N
		GENRL	Chills/ Chills	1	13AUG2020	4/2	1	No	O	NA	R (14AUG2020)	N/N
		MUSC	Back pain/ Lower Back Pain	1	14AUG2020	5/4	1	No	O	NA	R (17AUG2020)	N/N
		NERV	Headache/ Headache	2	08SEP2020	9/21	1	Yes		NA	R (28SEP2020)	N/N
>55/ C459100 1 1080 10801008	3^	GASTR	Nausea/ Nausea	2	31AUG2020	1/6	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1080 10801012	3^	NERV	Vomiting/ Vomiting	2	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
			Dizziness/ Light Headed	2	31AUG2020	1/1	1	No	O	NA	R (31AUG2020)	N/Y
			Headache/ Headaches worsening	2	31AUG2020	1/3	3	Yes		NA	R (02SEP2020)	N/N
	3^	GENRL	Chills/ Chills	2	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
			Pyrexia/ Fever of 101.7	2	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N
			Tooth abscess/ Tooth Abscess	2	20OCT2020	50/1	2	No	O	NA	R (20OCT2020)	N/N
			Osteoarthritis/ Osteoarthritis of the knee	2	26OCT2020	56/1	3	No	O	NA/TC/TCN	R (26OCT2020)	Y/N
	GASTR	Gastrointestinal disorder/ Bowel Problems	2	31OCT2020	61/C	3	No	O	NA/TC/TCN	N	Y/N	
>55/ C459100 1 1080 10801030	3^	INFEC	Kidney infection/ Kidney infection	1	24AUG2020	12/16	1	No	O	NA	R (08SEP2020)	N/N
>55/ C459100 1 1080 10801064	3^	EAR	Vertigo/ Vertigo	1	19AUG2020	1/27	3	No	O	NA/TC	R (14SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1080 10801066	3^	INJ&P	Ear injury/ Cut in Right Ear	2	26SEP2020	17/7	2	No	O	NA	R (02OCT2020)	N/N
>55/ C459100 1 1080 10801071	3^	GENRL	Chills/ CHILLS	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N
			Injection site pain/ PAIN AT INJECTION SIGHT	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N
		NERV	Lethargy/ LETHARGY	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N
		GENRL	Chills/ Chills	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
			Injection site erythema/ Redness at injection site	2	10SEP2020	1/4	2	Yes		NA	R (13SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	10SEP2020	1/4	2	Yes		NA	R (13SEP2020)	N/N
			Pyrexia/ Fever	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1080 10801083	3^	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1080 10801086	3^	SKIN	Pain of skin/ Sore Skin, Whole Body	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
		NERV	Dizziness/ Lightheadedness	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1080 10801094	3^	GASTR	Diarrhoea/ Sporadic Diarrhea	2	17SEP2020	4/3	2	Yes		NA	R (19SEP2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Pain	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
		NERV	Pain in extremity/ Sore L arm	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1080 10801121	3^	MUSC	Headache/ headache	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1080 10801121	3^	MUSC	Back pain/ Lower backpain	1	30AUG2020	3/15	2	No	O	NA/TC	R (13SEP2020)	N/N
>55/ C459100 1 1080 10801134	3^	GENRL	Pain/ Generalized body aches	1	02SEP2020	1/3	2	Yes		NA	R (04SEP2020)	N/N
		GASTR	Nausea/ Nausea	1	03SEP2020	2/6	1	Yes		NA	R (08SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Oral discomfort/ Mouth hotness	1	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Injection site erythema/ Redness at injection site (R)	1	03SEP2020	2/5	1	Yes		NA	R (07SEP2020)	N/N
			Injection site swelling/ Arm swelling at injection site (R)	1	03SEP2020	2/5	2	Yes		NA	R (07SEP2020)	N/N
			Pyrexia/ Low grade fever (101 F)	1	03SEP2020	2/6	2	Yes		NA	R (08SEP2020)	N/N
		GENRL	Chills/ Chills	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
			Pain/ Generalised Body Aches	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1080 10801152	3^	METAB	Fluid retention/ Worsening of WATER RETENTION in lower extremities	1	16SEP2020	13/3	3	No	O	NA/TC	R (18SEP2020)	Y/N
		VASC	Hypertension/ Worsening of HYPERTENSION	1	16SEP2020	13/3	3	No	O	NA/TC	R (18SEP2020)	Y/N
>55/ C459100 1 1080 10801176	3^	GENRL	Chills/ Chills	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
			Fatigue/ Fatigue	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100	3^	GENRL	Fatigue/ Tiredness	1	12SEP2020	3/1	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1080 10801177		MUSC	Myalgia/ MUSCLE ACHES	1	12SEP2020	3/2	2	Yes		NA/TC	R (13SEP2020)	N/N
		UNC	BODY ACHES@@/ Body aches	1	15SEP2020	6/3	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1080 10801191	3^	UNC	BODY ACHE@@/ Body ache	2	20OCT2020	7/2	1	Yes		NA	R (21OCT2020)	N/N
			FEVER@@/ Fever	2	20OCT2020	7/2	1	Yes		NA	R (21OCT2020)	N/N
>55/ C459100 1 1081 10811024	3^	MUSC	Rotator cuff syndrome/ Right Rotator Cuff Tear	2	28OCT2020	57/1	2	No	O	NA/TCN	R (28OCT2020)	N/N
>55/ C459100 1 1081 10811026	3^	GASTR	Diarrhoea/ Diarrhea	1	13AUG2020	2/5	1	No	O	NA	R (17AUG2020)	N/N
		INFEC	Urinary tract infection/ Urinary Tract Infection	2	05OCT2020	34/12	1	No	O	NA/TC	R (16OCT2020)	N/N
		BLOOD	Anaemia/ Worsening of Anemia	2	11OCT2020	40/19	3	No	O	NA	R (29OCT2020)	N/N
		GASTR	Abdominal pain lower/ lower abdominal pain	2	11OCT2020	40/6	3	No	O	NA/TC/TCN	R (16OCT2020)	N/N
		NEOPL	Borderline serous tumour of ovary/	2	11OCT2020	40/6	3	No	O	NA/TC/TCN	R (16OCT2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1081 10811037	3^	MUSC	Serous borderline tumor of left ovary	2	28SEP2020	26/8	2	No	O	NA/TC	R (05OCT2020)	N/N
			Arthralgia/ Right Knee pain									
>55/ C459100 1 1081 10811043	3^	EAR	Osteoarthritis/ Osteoarthritis right knee (new onset)	2	28SEP2020	26/C	1	No	O	NA/TC	N	N/N
			Ear disorder/ Fluid in Lt ear									
>55/ C459100 1 1081 10811059	3^	NEOPL	Lipoma/ Lipoma on neck	1	28AUG2020	11/1	1	No	O	NA/TCN	R (28AUG2020)	N/N
>55/ C459100 1 1081 10811061	3^	BLOOD	Lymphadenopathy/ Lymphadenopathy Under left ear	2	10SEP2020	8/15	2	No	O	NA/TC	R (24SEP2020)	N/N
		SKIN	Dermatitis contact/ Contact Dermatitis on lower extremities									
>55/ C459100 1 1081 10811107	3^	GENRL	Chest pain/ Idiopathic chest pain	2	07OCT2020	22/2	2	No	O	NA	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1081 10811110	3^	INFEC	Empyema/ loculated empyema	2	11OCT2020	26/C	3	No	O	NA/TC	RG	Y/N
			Pneumonia/ Right lower lobe pneumonia	2	11OCT2020	26/C	3	No	O	NA/TC	RG	Y/N
>55/ C459100 1 1081 10811139	3^	INFEC	Bronchitis/ Worsening Bronchitis	1	12SEP2020	13/7	1	No	O	NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1081 10811150	3^	SKIN	Rash pruritic/ Pruritic rash, generalized	1	06SEP2020	6/15	2	No	O	NA/TC	R (20SEP2020)	N/N
>55/ C459100 1 1081 10811159	3^	INJ&P	Fall/ Fall while walking	1	03SEP2020	2/1	2	No	O	NA/TCN	R (03SEP2020)	N/N
			Foot fracture/ Broke Toes 2,3,& 4 on Lt Foot	1	03SEP2020	2/49	2	No	O	NA/TCN	R (21OCT2020)	N/N
			Ligament sprain/ Sprained Rt Ankle	1	03SEP2020	2/49	2	No	O	NA/TCN	R (21OCT2020)	N/N
>55/ C459100 1 1081 10811162	3^	INFEC	Cellulitis/ Cellulitis of great toe on RT foot	1	11SEP2020	10/11	1	No	O	NA/TC	R (21SEP2020)	N/N
>55/ C459100 1 1081 10811170	3^	INV	Prostatic specific antigen increased/ elevate prostate specific antigen	2	OCT2020	9/C	2	No	O	NA/TCN	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1081 10811179	3^	MUSC	Osteoarthritis/ worsening-Left Big Toe Osteoarthritis	2	14OCT2020	21/1	2	No	O	NA/TCN	R (14OCT2020)	N/N
>55/ C459100 1 1081 10811211	3^	MUSC	Arthritis/ Arthritis L knee	1	01OCT2020	15/5	2	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C459100 1 1082 10821017	3^	INFEC	Upper respiratory tract infection/ upper respiratory infection	2	14OCT2020	51/17	2	No	O	NA/TC	R (30OCT2020)	N/N
>55/ C459100 1 1082 10821055	3^	GENRL	Swelling face/ facial swelling	2	10OCT2020	45/6	1	No	O	NA/TC	R (15OCT2020)	N/N
		SKIN	Rash/ rash to trunk	2	10OCT2020	45/6	1	No	O	NA/TC	R (15OCT2020)	N/N
		SKIN	Rash/ rash/skin irritation (dorsal side above sacrum, bilaterally below cervical vertebrae)	2	28OCT2020	63/8	1	No	O	NA/TC	R (04NOV2020)	N/N
>55/ C459100 1 1082 10821076	3^	HEPAT	Cholelithiasis/ cholelithiasis	1	13AUG2020	7/3	3	No	O	NA/TCN	R (15AUG2020)	Y/N
>55/ C459100 1 1082 10821094	3^	METAB	Diabetes mellitus/ diabetes	2	05NOV2020	66/C	1	No	O	NA/TC	N	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1082 10821167	3^	MUSC	Muscle spasms/ muscle spasms	2	20OCT2020	9/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1083 10831003	2^	SKIN	Hyperhidrosis/ Intermittent Profuse Sweating	2	28AUG2020	8/7	1	Yes		NA	R (03SEP2020)	N/N
>55/ C459100 1 1083 10831014	3^	INJ&P	Fall/ Fall	1	01AUG2020	2/1	1	No	O	NA/TC	R (01AUG2020)	N/N
		MUSC	Arthralgia/ Right Knee Pain	1	01AUG2020	2/2	1	No	O	NA/TC	R (02AUG2020)	N/N
>55/ C459100 1 1083 10831016	3^	INJ&P	Ligament sprain/ Sprained Left Knee	2	14SEP2020	25/C	2	No	O	NA	N	N/N
		MUSC	Osteoarthritis/ Osteoarthritis-Left knee	2	16SEP2020	27/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1083 10831027	3^	MUSC	Muscle spasms/ Leg cramps	1	11AUG2020	8/13	1	No	O	NA	R (23AUG2020)	N/N
		MUSC	Muscle spasms/ Leg Cramps	1	24AUG2020	21/32	1	No	O	NA	R (24SEP2020)	N/N
>55/ C459100 1 1083 10831031	3^	RESP	Cough/ Intermittent Cough	1	20AUG2020	17/2	1	No	O	NA	R (21AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1083 10831050	3^	NEOPL	Lipoma/ Lipoma-Behind the Right Elbow	2	27SEP2020	35/C	1	No	O	NA	N	N/N
		MUSC	Musculoskeletal stiffness/ Neck Stiffness	1	29AUG2020	25/4	1	No	O	NA	R (01SEP2020)	N/N
		INJ&P	Fall/ Fall	1	01SEP2020	28/1	2	No	O	NA	R (01SEP2020)	N/N
		MUSC	Rotator cuff syndrome/ Rotator Cuff Separation-Right	1	01SEP2020	28/C	2	No	O	NA	RG	N/N
		INJ&P	Contusion/ Bruising-Bilateral Legs	2	30SEP2020	28/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1083 10831075	3^	INJ&P	Fall/ Fall	2	30SEP2020	28/1	1	No	O	NA	R (30SEP2020)	N/N
			Skin abrasion/ Scraping -Bilateral Legs	2	30SEP2020	28/C	1	No	O	NA	RG	N/N
			Muscle strain/ Intermittent Muscle Strain-Under Left Armpit	2	26OCT2020	57/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1083 10831077	3^	SKIN	Dermatitis contact/ Contact Dermatitis-Chest	1	01SEP2020	23/23	2	No	CD	NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1083 10831103	3^	METAB	Hypercholesterolaemia/ Hypercholesterolemia	1	27AUG2020	14/C	1	No	CD	NA/TC	N	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1083 10831104	3^	MUSC	Back pain/ Low back Pain	1	23AUG2020	10/C	1	No	O	NA/TC	N	N/N
		MUSC	Pain in extremity/ Bilateral Thumb Pain	1	26AUG2020	13/C	1	No	O	NA	N	N/N
>55/ C459100 1 1083 10831134	3^	GENRL	Injection site pain/ Intermittent Pain at injection site- Right*		20AUG2020	1/C	1	Yes		NA	RG	N/N
>55/ C459100 1 1083 10831144	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	31AUG2020	8/16	1	No	O	NA/TC	R (15SEP2020)	N/N
>55/ C459100 1 1083 10831149	3^	SKIN	Rash/ Rash-Upper thighs,chest,axillary-Bilateral	1	28AUG2020	5/3	1	Yes		NA/TC	R (30AUG2020)	N/N
>55/ C459100 1 1083 10831173	3^	INFEC	Tooth infection/ Tooth Infection	1	12OCT2020	47/23	2	No	O	NA	R (03NOV2020)	N/N
		NEOPL	Prostate cancer/ Prostate Cancer	1	02NOV2020	68/C	2	No	O	NA/TCN	N	N/N
>55/ C459100 1 1083 10831218	3^	GENRL	Injection site pain/ Injection Site Pain-Left Deltoid	1	30SEP2020	21/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		GENRL	Pain/ Body Aches	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1083 10831224	3^	GASTR	Large intestine polyp/ Colon Polyps-Benign	1	21SEP2020	11/C	1	No	O	NA	N	N/N
>55/ C459100 1 1083 10831229	3^	MUSC	Arthralgia/ Joint Pain-Wrist and Shoulder	1	12SEP2020	2/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1083 10831234	3^	INJ&P	Fall/ Traumatic fall	2	08OCT2020	8/1	1	No	O	NA	R (08OCT2020)	N/N
			Joint dislocation/ Open wound dislocation Left 5th Finger	2	08OCT2020	8/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1083 10831236	3^	GASTR	Flatulence/ Gas Pain Gastrointestinal Discomfort	1	23SEP2020	13/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1083 10831237	3^	INV	Blood testosterone increased/ High Testosterone	2	07OCT2020	8/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1083 10831257	3^	INJ&P	Epicondylitis/ Tennis Elbow-Left	1	29SEP2020	7/23	1	No	O	NA/TC	R (21OCT2020)	N/N
		GENRL	Injection site pain/ Right Arm Pain at Injection Site	1	13OCT2020	21/2	1	Yes		NA/TC	R (14OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site swelling/ 2cm swelling at Injection Site Right Arm	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
		MUSC	Arthralgia/ Joint Pain- Knees,Hips,Toes,Fingers	2	14OCT2020	2/1	2	Yes		NA/TC	R (14OCT2020)	N/N
			Myalgia/ Muscle Body Aches	2	14OCT2020	2/1	2	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C459100 1 1084 10841011	3^	INJ&P	Muscle strain/ LEFT CALF STRAIN	2	24AUG2020	7/32	2	No	O	NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1084 10841032	3^	EYE	Vitreous detachment/ posterior vitreous detachment left eye	2	16SEP2020	24/C	1	No	O	NA	N	N/N
>55/ C459100 1 1084 10841049	3^	SKIN	Pruritus/ Pruritus	2	21SEP2020	27/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1084 10841077	3^	IMMUN	Seasonal allergy/ seasonal allergies	1	14AUG2020	8/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1084 10841093	3^	MUSC	Joint noise/ Clicking in the Left forearm*		07AUG2020	1/C	1	No	O	NA	RG	N/N
>55/ C459100	3^	MUSC	Pain in jaw/ Jaw pain	2	14SEP2020	15/8	1	No	O	NA	R (21SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1084 10841103		NERV	Headache/ Headache	2	14SEP2020	15/1	1	No	O	NA	R (14SEP2020)	N/N
>55/ C459100 1 1084 10841108	3^	GASTR	Constipation/ CONSTIPATION	1	17AUG2020	8/16	2	No	O	NA	R (01SEP2020)	N/N
>55/ C459100 1 1084 10841135	3^	INFEC	Localised infection/ Right Greater Toe Infection	1	22AUG2020	11/C	3	No	O	NA/TCN	N	N/N
>55/ C459100 1 1084 10841147	3^	SKIN	Rash pruritic/ Pruitic/Burning Rash to Left and Right First and Second Interphalangeal Spaces	1	19AUG2020	8/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1084 10841158	3^	INFEC	Fungal skin infection/ worsening skin fungal infection to groin area	2	SEP2020	1/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1084 10841162	3^	NERV	Syncope/ Syncope	2	05SEP2020	2/1	1	No	O	NA	R (05SEP2020)	N/N
		INV	Blood glucose increased/ Elevated Blood Glucose	2	14SEP2020	11/3	2	No	O	NA/TC	R (16SEP2020)	N/N
>55/ C459100	3^	METAB	Diabetes mellitus inadequate control/	1	22AUG2020	9/12	2	No	O	NA/TC	R (02SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1084 10841173			UNCONTROLLED DIABETES MELLITUS TYPE II									
>55/ C459100 1 1084 10841180	3^	METAB	Vitamin D deficiency/ Vitamin D deficiency	1	31AUG2020	18/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1084 10841183	3^	GENRL	Injection site pain/ Moderate Injection Site Pain	1	15AUG2020	2/2	1	Yes		NA	R (16AUG2020)	N/N
		MUSC	Myalgia/ muscle pain to lower extremities	2	05SEP2020	2/4	2	Yes		NA	RS (08SEP2020)	N/N
>55/ C459100 1 1084 10841196	3^	RESP	Dyspnoea/ shortness of breath	2	04OCT2020	26/1	1	No	O	NA	R (04OCT2020)	N/N
>55/ C459100 1 1084 10841219	3^	REPRO	Ovarian cyst/ Left ovarian cyst, benign tumor	1	24AUG2020	8/27	2	No	O	NA/TC/TCN	R (19SEP2020)	Y/N
			Uterine prolapse/ Prolapsed uterus	1	24AUG2020	8/27	2	No	O	NA/TC/TCN	R (19SEP2020)	Y/N
>55/ C459100 1 1084 10841221	3^	INFEC	Sinusitis/ Sinus Infection	2	23OCT2020	45/C	3	No	CD	NA	RG	N/N
>55/ C459100	3^	EYE	Diabetic retinopathy/ Right Eye Diabetic Retinopathy	2	21SEP2020	11/C	2	No	O	NA/TC/TCN	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1084 10841235 >55/ C459100	3^	INFEC	Tooth infection/ Upper Left Tooth Infection	2	28SEP2020	20/16	1	No	O	NA	R (13OCT2020)	N/N
1 1084 10841246 >55/ C459100	3^	INFEC	Eye infection/ Right Eye Infection	1	29AUG2020	8/C	2	No	O	NA/TC	N	N/N
1 1084 10841258 >55/ C459100	3^	INFEC	Hordeolum/ Right Eye Stye	1	13SEP2020	19/26	1	No	O	NA/TC	R (08OCT2020)	N/N
1 1084 10841293 >55/ C459100	3^	NERV	Headache/ Headache	1	05SEP2020	11/1	1	No	O	NA/TC	R (05SEP2020)	N/N
1 1084 10841297 >55/ C459100	3^	INV	Hepatic enzyme increased/ Elevated liver enzymes	1	16SEP2020	17/C	1	No	O	NA	N	N/N
1 1084 10841329 >55/ C459100	3^	MUSC	Back pain/ Sharp Pain in Lower Right Back	1	15SEP2020	7/C	2	No	O	NA	N	N/N
1 1084 10841367 >55/ C459100	3^	INJ&P	Stoma site rash/ Rash to Abdomen Around Ostomy Bag	1	15SEP2020	5/10	2	No	CD	NA/TC	R (24SEP2020)	N/N
1 1084 10841377												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1084 10841380	3^	SKIN	Rash/ Rash on cheek	2	21OCT2020	20/7	2	No	O	NA/TC	R (27OCT2020)	N/N
>55/ C459100 1 1084 10841397	3^	INJ&P	Ankle fracture/ broken ankle	1	01OCT2020	18/C	2	No	O	NA/TCN	N	N/N
>55/ C459100 1 1084 10841398	3^	NERV	Fall/ Fall Syncope/ Fainted	1	01OCT2020	18/1	2	No	O	NA	R (01OCT2020)	N/N
>55/ C459100 1 1084 10841398	3^	NERV	Syncope/ Fainted	2	28OCT2020	24/1	1	No	O	NA	R (28OCT2020)	N/N
>55/ C459100 1 1084 10841440	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	2	15OCT2020	2/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1084 10841471	3^	INJ&P	Contusion/ Left Bruised Heel	1	05OCT2020	6/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C459100 1 1085 10851073	3^	INFEC	Respiratory tract infection viral/ Viral Respiratory Infection	2	08SEP2020	13/11	1	No	O	NA	R (18SEP2020)	N/N
>55/ C459100 1 1085 10851168	3^	GENRL	Chills/ CHILLS	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1085 10851183	3^	GASTR	Pyrexia/ FEVER	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
			Diarrhoea/ Diarrhea	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ Fever	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Headache/ Headache	2	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C459100 1 1085 10851216	3^	INJ&P	Oropharyngeal pain/ Sore throat	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
			Fall/ Fall in hole	2	17OCT2020	25/1	1	No	O	NA	R (17OCT2020)	N/N
			Lower limb fracture/ Left leg fracture of tibia/fibula	2	17OCT2020	25/2	1	No	O	NA/TC/TCN	R (18OCT2020)	Y/N
>55/ C459100 1 1085 10851268	3^	GENRL	Chills/ Chills	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N
			Pyrexia/ Fever	2	01OCT2020	1/3	2	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100	3^	GENRL	Injection site urticaria/ Localized Urticaria Injection Site	2	05OCT2020	5/2	1	Yes		NA	R (06OCT2020)	N/N
			Pain/ body aches	2	05OCT2020	4/2	1	Yes		NA/TC	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1085 10851293 >55/ C459100	3^	GENRL	Injection site pain/ injection site pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
1 1085 10851318 >55/ C459100	3^	GENRL	Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
1 1085 10851324 >55/ C459100	3^	GASTR	Diarrhoea/ Diarrhea	1	20SEP2020	7/1	1	Yes		NA	R (20SEP2020)	N/N
1 1085 10851326 >55/ C459100	3^	INJ&P	Arthropod bite/ ANT BITES	1	14AUG2020	9/2	1	No	O	NA/TC	R (15AUG2020)	N/N
1 1087 10871003 >55/ C459100	3^	EYE	Cataract/ WORSENING OF CATARACTS (RIGHT EYE)	1	21AUG2020	15/1	1	No	O	NA/TC/TCN	R (21AUG2020)	N/N
1 1087 10871009 >55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	12OCT2020	42/C	2	No	CD	NA	N	N/N
1 1087 10871022 >55/ C459100	3^	GASTR	Diarrhoea/ Loose Bowel Movement	2	08SEP2020	14/1	1	No	O	NA	R (08SEP2020)	N/N
1 1087 10871023												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Arthralgia/ generalized joint pain	2	17OCT2020	53/2	1	No	O	NA	R (18OCT2020)	N/N
>55/ C459100 1 1087 10871024	3^	INFEC	Cellulitis/ CELLULITIS R HAND MIDDLE FINGER	1	13AUG2020	7/58	2	No	O	NA/TC	R (09OCT2020)	N/N
>55/ C459100 1 1087 10871029	3^	GENRL	Fatigue/ Fatigue	2	31AUG2020	6/2	1	Yes		NA	R (01SEP2020)	N/N
		GASTR	Abdominal pain/ Functional Abdominal Pain	2	28OCT2020	64/9	2	No	O	NA/TC	R (05NOV2020)	N/N
			Diverticulum/ Diverticulosis	2	28OCT2020	64/C	2	No	O	NA	N	N/N
			Hiatus hernia/ Small Hiatal Hernia	2	28OCT2020	64/C	1	No	O	NA	N	N/N
		HEPAT	Gallbladder disorder/ Distended Gallbladder	2	28OCT2020	64/C	1	No	O	NA	N	N/N
		INFEC	Urinary tract infection/ Urinary Tract Infection	2	28OCT2020	64/9	2	No	O	NA	R (05NOV2020)	N/N
		NERV	Toxic encephalopathy/ Acute Toxic Metabolic Encephalopathy	2	28OCT2020	64/9	3	No	CD	NA/TC	R (05NOV2020)	Y/N
>55/ C459100 1 1087 10871031	3^	MUSC	Arthralgia/ RIGHT KNEE PAIN	2	08SEP2020	14/C	2	No	O	NA/TC	RG	N/N
>55/ C459100	3^	INFEC	Ear infection/ EAR INFECTION (RIGHT)	2	13SEP2020	18/12	2	No	O	NA/TC	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1087 10871037 >55/ C459100	3^	SKIN	Rosacea/ Worsening of Rosacea	2	07SEP2020	8/7	1	No	O	NA/TC	R (13SEP2020)	N/N
1 1087 10871043 >55/ C459100	3^	GASTR	Diarrhoea/ DIARRHEAL EPISODE	1	30AUG2020	21/2	1	No	O	NA	R (31AUG2020)	N/N
1 1087 10871048 >55/ C459100	3^	INFEC	Sinusitis/ SINUS INFECTION	2	21SEP2020	22/7	1	No	O	NA/TC	R (27SEP2020)	N/N
1 1087 10871057 >55/ C459100	3^	GASTR	Nausea/ NAUSEA	2	14SEP2020	15/22	1	No	O	NA/TC	R (05OCT2020)	N/N
1 1087 10871070 >55/ C459100	3^	CARD	Acute coronary syndrome/ ACUTE CORONARY SYNDROME	2	08SEP2020	8/3	3	No	O	NA/TC/TCN	R (10SEP2020)	Y/N
1 1087 10871090 >55/ C459100	3^	GENRL	Angina unstable/ UNSTABLE ANGINA	2	08SEP2020	8/3	2	No	O	NA	R (10SEP2020)	N/N
1 1087 10871090 >55/ C459100	3^	GENRL	Chills/ Chills	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
1 1087 10871090 >55/ C459100	3^	GENRL	Pyrexia/ Fever	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1087 10871121	3^	BLOOD	Blood loss anaemia/ Acute blood loss anemia	1	07SEP2020	20/3	3	No	O	NA	R (09SEP2020)	N/N
			Thrombocytopenia/ Thrombocytopenia	1	07SEP2020	20/C	3	No	O	NA	N	N/N
			GASTR Gastrointestinal haemorrhage/ GI Bleed	1	07SEP2020	20/3	3	No	O	P/TC/TCN/W	R (09SEP2020)	Y/N
			Haematochezia/ Hematochezia	1	07SEP2020	20/3	3	No	O	NA/TC	R (09SEP2020)	N/N
			Oesophageal ulcer/ Worsening of esophageal ulcers	1	07SEP2020	20/3	3	No	O	NA/TC/TCN	R (09SEP2020)	N/N
			Varices oesophageal/ Worsening of esophageal varices	1	07SEP2020	20/3	3	No	O	NA/TC/TCN	R (09SEP2020)	N/N
			HEPAT Cirrhosis alcoholic/ Worsening of alcoholic cirrhosis	1	07SEP2020	20/C	3	No	O	NA	N	N/N
METAB Hypernatraemia/ Hypernatremia	1	07SEP2020	20/3	2	No	O	NA	R (09SEP2020)	N/N			
>55/ C459100 1 1087 10871124	3^	NEOPL Acrochordon/ WORSENING OF Skin Tag - eye, bilateral	1	08SEP2020	21/1	1	No	O	NA/TCN	R (08SEP2020)	N/N	
		NEOPL Glomus tumour/ WORSENING OF BENIGN GLOMUS TUMOR ON LEFT RING FINGER	2	15SEP2020	7/1	2	No	O	NA/TCN	R (15SEP2020)	N/N	
>55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	25AUG2020	7/10	2	No	O	NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1087 10871125		METAB	Dehydration/ Dehydration	1	25AUG2020	7/10	1	No	O	NA	R (03SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	08OCT2020	30/1	1	No	O	NA	R (08OCT2020)	N/N
>55/ C459100 1 1087 10871128	3^	GENRL	Fatigue/ FATIGUE	2	11SEP2020	2/5	1	Yes		NA	R (15SEP2020)	N/N
		RESP	Cough/ COUGH	2	25SEP2020	16/14	1	No	O	NA	R (08OCT2020)	N/N
>55/ C459100 1 1087 10871150	3^	INFEC	Pharyngitis streptococcal/ STREP THROAT	1	01SEP2020	12/5	3	No	O	NA/TC	R (05SEP2020)	Y/N
>55/ C459100 1 1087 10871156	3^	NEOPL	Squamous cell carcinoma of skin/ SQUAMOUS CELL CARCINOMA (RIGHT, FACE)	1	01SEP2020	12/43	2	No	O	NA	R (13OCT2020)	N/N
>55/ C459100 1 1087 10871161	3^	RESP	Oropharyngeal pain/ Sore Throat	1	28AUG2020	8/4	1	No	O	NA	R (31AUG2020)	N/N
>55/ C459100 1 1087 10871169	3^	GENRL	Chills/ Chills	1	12SEP2020	20/1	1	No	O	NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ Chills	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
			Fatigue/ Fatigue	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		MUSC	Myalgia/ generalized muscle Soreness	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1087 10871170	3^	NEOPL	Malignant melanoma of eyelid/ MELANOMA OF RIGHT LOWER EYELID	2	21SEP2020	8/C	3	No	O	NA	N	N/N
>55/ C459100 1 1087 10871183	3^	INFEC	Urinary tract infection/ UTI	1	31AUG2020	7/8	1	No	O	NA/TC	R (07SEP2020)	N/N
>55/ C459100 1 1087 10871187	3^	MUSC	Osteoarthritis/ OSTEOARTHRITIS RIGHT KNEE	1	02SEP2020	9/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1087 10871190	3^	GENRL	Chills/ CHILLS	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100	3^	NERV	Neuropathy peripheral/ WORSENING OF NEUROPATHY	1	08SEP2020	15/29	2	No	O	NA/TCN	R (06OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1087 10871200		INFEC	Cystitis/ BLADDER INFECTION	2	10OCT2020	26/C	2	No	O	NA/TC	RG	N/N
		RENAL	Haematuria/ HEMATURIA	2	10OCT2020	26/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1087 10871204	3^	RESP	Rhinorrhoea/ RUNNY NOSE	2	27SEP2020	13/8	1	No	O	NA	R (04OCT2020)	N/N
>55/ C459100 1 1087 10871222	3^	EYE	Vitreous detachment/ POSTERIOR VITREOUS DETACHMENT	1	03SEP2020	9/C	2	No	O	NA	N	N/N
		GASTR	Diarrhoea/ DIARRHEA	2	17SEP2020	4/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1087 10871223	3^	VASC	Flushing/ FACIAL FLUSHING	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1087 10871224	3^	INFEC	Gingival abscess/ ABSCCESS ON GUM	1	04SEP2020	10/14	2	No	O	NA/TC/TCN	R (17SEP2020)	N/N
>55/ C459100 1 1087 10871228	3^	CARD	Atrial fibrillation/ PAROXYSMAL ATRIAL Fibrillation	1	03SEP2020	9/6	2	No	O	NA	R (08SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Cardiac failure congestive/ Worsening of Chronic Congestive Heart Failure	1	03SEP2020	9/6	3	No	O	P/TC/W	R (08SEP2020)	Y/N
		INFECTION	Urinary tract infection/ Urinary Tract Infection	1	03SEP2020	9/6	2	No	O	NA/TC	R (08SEP2020)	N/N
		METABOLISM	Dehydration/ DEHYDRATION	1	03SEP2020	9/2	2	No	O	NA/TCN	R (04SEP2020)	N/N
		RENAL	Acute kidney injury/ Acute Kidney Injury	1	03SEP2020	9/5	2	No	O	NA	R (07SEP2020)	N/N
		RESPIRATORY	Acute respiratory failure/ Acute Respiratory Failure	1	03SEP2020	9/2	3	No	O	NA/TC	R (04SEP2020)	N/N
			Dyspnoea/ SHORTNESS OF BREATH	1	03SEP2020	9/2	3	No	O	NA	R (04SEP2020)	N/N
			Pulmonary oedema/ BILATERAL PULMONARY EDEMA	1	03SEP2020	9/3	2	No	O	NA	R (05SEP2020)	N/N
		VASCULAR	Accelerated hypertension/ Accelerated Hypertension	1	03SEP2020	9/4	3	No	O	NA	R (06SEP2020)	N/N
		METABOLISM	Hypokalaemia/ HYPOKALEMIA	1	04SEP2020	10/3	2	No	O	NA/TC	R (06SEP2020)	N/N
		GENERAL	Pyrexia/ LOW-GRADE FEVER	1	05SEP2020	11/2	2	No	O	NA	R (06SEP2020)	N/N
		MUSCULOSKELETAL	Pain in extremity/ WORSENING OF BILATERAL FOOT PAIN	1	05SEP2020	11/2	2	No	O	NA/TC	R (06SEP2020)	N/N
		NERVOUS	Dizziness/ Dizziness	1	05SEP2020	11/4	2	No	O	NA/TCN	R (08SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		VASC	Hypotension/ Hypotension	1	05SEP2020	11/3	2	No	O	NA	R (07SEP2020)	N/N
>55/ C459100 1 1087 10871232	3^	EAR	Ear pain/ ear ache	2	01OCT2020	16/1	1	No	O	NA	R (01OCT2020)	N/N
>55/ C459100 1 1087 10871238	3^	RESP	Asthma/ WORSENING OF ASTHMA	1	30AUG2020	5/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1087 10871256	3^	GASTR	Diarrhoea/ DIARRHEAL EPISODE	1	06SEP2020	7/3	1	No	O	NA	R (08SEP2020)	N/N
>55/ C459100 1 1087 10871257	3^	GENRL	Pyrexia/ FEVER	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1087 10871275	3^	GASTR	Paraesthesia oral/ TONGUE TINGLING	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/Y
>55/ C459100 1 1087 10871284	3^	NEOPL	Basal cell carcinoma/ BASAL CELL CARCINOMA OF LEFT EYE LID	1	08SEP2020	8/30	2	No	O	NA/TCN	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1087 10871291	3^	MUSC	Arthralgia/ WORSENING OF RIGHT KNEE PAIN	1	14SEP2020	14/40	1	No	O	NA/TC	R (23OCT2020)	N/N
>55/ C459100 1 1087 10871304	3^	INJ&P	Tooth fracture/ CRACKED TOOTH	2	28SEP2020	8/8	2	No	O	NA/TCN	R (05OCT2020)	N/N
>55/ C459100 1 1087 10871317	3^	GASTR	Gastroesophageal reflux disease/ new onset gastroesophageal reflux disease	2	24SEP2020	2/C	1	No	O	NA/TC	N	N/N
		RESP	Nasal polyps/ new onset nasal polyps	2	24SEP2020	2/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1087 10871331	3^	MUSC	Pain in extremity/ Left Arm Soreness	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA	1	09SEP2020	7/1	1	No	O	NA	R (09SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	22SEP2020	20/14	1	No	O	NA	R (05OCT2020)	N/N
>55/ C459100 1 1087 10871334	3^	MUSC	Back pain/ WORSENING OF BACK PAIN	2	20OCT2020	29/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1087 10871370	3^	INFEC	Otitis media acute/ ACUTE OTITIS MEDIA (LEFT)	2	18OCT2020	19/7	2	No	O	NA/TC	R (24OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1087 10871371	3^	NERV	Cervical radiculopathy/ cervical radiculopathy	2	19OCT2020	20/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1087 10871385	3^	REPRO	Benign prostatic hyperplasia/ WORSENING OF BENIGN PROSTATIC HYPERPLASIA*		10SEP2020	-5/22	2	No	O	NA/TC	R (01OCT2020)	N/N
		RESP	Rhinitis perennial/ WORSENING OF PERENNIAL ALLERGIC RHINITIS	1	28SEP2020	14/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1087 10871392	3^	SKIN	Actinic keratosis/ Actinic Keratosis	2	12OCT2020	13/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1087 10871396	3^	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
			Injection site pain/ Soreness at Injection Site	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
			Pyrexia/ Fever	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
>55/ C459100 1 1087 10871397	3^	INFEC	Sinusitis/ Sinus Infection	2	07OCT2020	7/10	2	No	O	NA/TC	R (16OCT2020)	N/N
>55/ C459100	3^	RESP	Oropharyngeal pain/ Sore Throat	1	17SEP2020	8/2	1	No	O	NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1087 10871407 >55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
1 1087 10871416 >55/ C459100	3^	RESP	Pyrexia/ Fever Asthma/ ASTHMA EXACERBATION	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
1 1087 10871418 >55/ C459100	3^	RESP	Asthma/ ASTHMA EXACERBATION	1	16SEP2020	7/10	2	No	O	NA/TC	R (25SEP2020)	N/N
1 1087 10871422 >55/ C459100	3^	MUSC	Muscle spasms/ RIGHT ARM MUSCLE SPASM	1	12SEP2020	2/C	1	Yes		NA/TC	N	N/N
1 1087 10871430 >55/ C459100	3^	GENRL	Myalgia/ GENERALIZED RIGHT ARM MUSCLE PAIN	1	12SEP2020	2/C	1	Yes		NA	N	N/N
1 1087 10871430 >55/ C459100	3^	GENRL	Chills/ CHILLS	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
1 1087 10871431 >55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
1 1087 10871431		NERV	Headache/ Headache	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Rhinitis allergic/ Allergic Rhinitis	2	22OCT2020	22/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1087 10871432	3^	GENRL	Chills/ CHILLS	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
			Pyrexia/ FEVER	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
>55/ C459100 1 1087 10871442	3^	GENRL	Pyrexia/ fever	1	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	06OCT2020	2/4	2	Yes		NA	R (09OCT2020)	N/N
			Nausea/ Nausea	2	06OCT2020	2/4	2	Yes		NA	R (09OCT2020)	N/N
		GENRL	Pyrexia/ fever	2	06OCT2020	2/4	2	Yes		NA	R (09OCT2020)	N/N
		NERV	Dizziness/ lightheadedness	2	06OCT2020	2/4	2	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1087 10871450	3^	GENRL	Fatigue/ fatigue	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pain/ body aches	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ fever	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
>55/ C459100 1 1087 10871463	3^	INFE	Cellulitis/ CELLULITIS RIGHT LEG	1	29SEP2020	14/7	2	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C459100 1 1087 10871466	3^	INV	Prostatic specific antigen increased/ PSA LEVELS ELEVATED	1	28SEP2020	13/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1087 10871478	3^	MUSC	Spinal osteoarthritis/ Osteoarthritis - Spine	2	28OCT2020	20/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1087 10871495	3^	VASC	Hypertension/ WORSENING OF HYTPERTENSION	2	19OCT2020	8/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1087 10871502	3^	REPRO	Erectile dysfunction/ ERECTILE DYSFUNCTION	2	30OCT2020	19/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1087 10871524	3^	EAR	Vertigo/ VERTIGO	1	02OCT2020	8/C	2	No	O	NA/TC	RG	N/N
>55/ C459100	3^	INJ&P	Fall/ Subject fell	1	30AUG2020	4/1	1	No	O	NA/TCN	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1088 10881105			Humerus fracture/ Fractured Left Humerus	1	30AUG2020	4/1	2	No	O	NA/TCN	R (30AUG2020)	N/N
		INFEC	Urinary tract infection/ Urinary Tract Infection	1	06SEP2020	11/14	2	No	CD	NA/TC	R (19SEP2020)	N/N
>55/ C459100 1 1088 10881106	3^	INFEC	Herpes zoster/ Subject diagnosed with shingles on back of neck and side of face	2	06OCT2020	22/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1088 10881164	3^	INFEC	Sinusitis/ sinus infection	1	14SEP2020	7/16	2	No	O	NA/TC	R (29SEP2020)	N/N
		INFEC	Sinusitis/ SINUS INFECTION	2	23OCT2020	25/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1088 10881178	3^	INJ&P	Wrist fracture/ Broken left wrist	1	23OCT2020	16/C	2	No	O	NA/TCN	RG	N/N
>55/ C459100 1 1088 10881202	3^	MUSC	Pain in extremity/ Soreness/arm pain in left arm	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
>55/ C459100 1 1089 10891004	2^	INV	White blood cell count increased/ elevated white count	1	10AUG2020	13/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1089 10891026	3^	GASTR	Nausea/ Nausea	2	14SEP2020	27/1	2	No	O	NA	R (14SEP2020)	N/N
>55/ C459100 1 1089 10891042	3^	INV	Blood cholesterol increased/ Elevated Cholesterol	1	AUG2020	1/C	2	No	O	NA/TC	N	N/N
		BLOOD	Lymphadenopathy/ Left Para clavicular lymph node enlargement	2	28AUG2020	3/68	1	Yes		NA	R (03NOV2020)	N/N
>55/ C459100 1 1089 10891093	3^	INJ&P	Fall/ Fell out of Bed	1	15AUG2020	6/1	1	No	O	NA	R (15AUG2020)	N/N
			Muscle strain/ pulled muscle right arm	1	15AUG2020	6/	2	No	O	NA/TC	R	N/N
>55/ C459100 1 1089 10891110	3^	MUSC	Back pain/ Back Pain	1	15AUG2020	4/6	1	No	O	NA/TC	R (20AUG2020)	N/N
>55/ C459100 1 1089 10891112	3^	INFEC	Fungal infection/ fungal infection bilateral axilla	2	18SEP2020	18/9	2	No	O	NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1089 10891150	3^	CARD	Atrial fibrillation/ Chronic atrial fibrillation with RVR'	2	04OCT2020	26/2	3	No	O	NA/TC/TCN	R (05OCT2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1089 10891160	3^	INJ&P	Ankle fracture/ right ankle fracture	1	07SEP2020	19/C	2	No	O	NA	N	N/N
			Fall/ fall	1	07SEP2020	19/1	2	No	O	NA	R (07SEP2020)	N/N
>55/ C459100 1 1089 10891169	3^	EAR	Vertigo/ worsening of Vertigo	2	09SEP2020	1/3	1	No	O	NA	R (11SEP2020)	N/N
>55/ C459100 1 1089 10891190	3^	NERV	Sciatica/ sciatic pain	2	17OCT2020	32/C	1	No	O	NA	N	N/N
>55/ C459100 1 1089 10891242	3^	REPRO	Benign prostatic hyperplasia/ BPH	2	20OCT2020	28/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1089 10891282	3^	NERV	Nerve compression/ pinched nerve back	2	07OCT2020	7/7	2	No	O	NA/TC	R (13OCT2020)	N/N
>55/ C459100 1 1089 10891322	3^	INFEC	Conjunctivitis/ left pink eye	1	30SEP2020	15/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1090 10901027	3^	RENAL	Nephrolithiasis/ kidney stone	2	11SEP2020	19/4	3	No	O	NA/TC	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1090 10901060	3^	INJ&P	Muscle strain/ pulled hamstring, left	2	23SEP2020	27/8	2	No	O	NA/TC	R (30SEP2020)	N/N
		MUSC	Arthralgia/ right shoulder pain	2	26SEP2020	30/1	1	No	O	NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1090 10901078	3^	VASC	Lymphorrhoea/ lymph fluid leakage, left groin area	2	31AUG2020	4/6	1	No	O	NA/TC	R (05SEP2020)	N/N
>55/ C459100 1 1090 10901080	3^	SKIN	Drug eruption/ drug eruption rash	2	20SEP2020	24/23	2	No	O	NA/TC	R (12OCT2020)	N/N
>55/ C459100 1 1090 10901083	3^	INJ&P	Ligament sprain/ left ankle, twisted	2	12SEP2020	16/26	1	No	O	NA/TC	R (07OCT2020)	N/N
>55/ C459100 1 1090 10901089	3^	RENAL	Haematuria/ hematuria	2	18SEP2020	22/13	2	No	O	NA/TC	R (30SEP2020)	N/N
>55/ C459100 1 1090 10901113	3^	ENDO	Goitre/ Goiter	1	08AUG2020	2/C	1	No	O	NA	N	N/N
>55/ C459100 1 1090 10901153	3^	MUSC	Arthralgia/ right thumb, joint pain	2	15SEP2020	16/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1090 10901158	3^	INFEC	Urinary tract infection/ UTI	1	15AUG2020	4/18	1	No	O	NA/TC	R (01SEP2020)	N/N
>55/ C459100 1 1090 10901162	3^	INJ&P	Contusion/ bruised right torso	2	23SEP2020	21/C	1	No	O	NA	RG	N/N
			Fall/ fall	2	23SEP2020	21/1	1	No	O	NA	R (23SEP2020)	N/N
>55/ C459100 1 1090 10901186	3^	EAR	Ear pain/ Earache	1	28AUG2020	15/5	1	No	O	NA	R (01SEP2020)	N/N
>55/ C459100 1 1090 10901189	3^	METAB	Type 2 diabetes mellitus/ diabetes type II	1	30AUG2020	17/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1090 10901196	3^	SKIN	Eczema/ worsening eczema, right elbow	2	25SEP2020	18/25	1	No	O	NA/TC	R (19OCT2020)	N/N
>55/ C459100 1 1090 10901202	3^	GENRL	Fatigue/ Fatigue	2	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
			Injection site pain/ Injection site pain-left arm	2	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
			Pain/ Body aches-generalized	2	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1090 10901209	3^	MUSC	Musculoskeletal stiffness/ stiffness in left arm	1	17AUG2020	1/4	2	Yes		NA/TC	R (20AUG2020)	N/N
>55/ C459100 1 1090 10901217	3^	GENRL	Injection site pain/ injection pain, left arm	1	17AUG2020	1/4	2	Yes		NA	R (20AUG2020)	N/N
>55/ C459100 1 1090 10901218	3^	GASTR	Dyspepsia/ Heart burn	2	22SEP2020	15/3	1	No	O	NA	R (24SEP2020)	N/N
>55/ C459100 1 1090 10901229	3^	CARD	Arrhythmia/ abnormal heart rhythm, idiopathic	2	14SEP2020	7/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1090 10901236	3^	INFEC	Sinusitis/ sinus infection, head	2	08OCT2020	29/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1090 10901237	3^	GENRL	Chills/ Chills	2	04SEP2020	1/2	2	Yes		NA/TC	R (05SEP2020)	N/N
		SKIN	Hyperhidrosis/ Sweats	2	04SEP2020	1/2	2	Yes		NA/TC	R (05SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1090 10901247	3^	NERV	Headache/ Headache	2	05SEP2020	2/2	1	Yes		NA/TC	R (06SEP2020)	N/N
		GENRL	Chills/ Chills	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
			Pain/ Body aches	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
>55/ C459100 1 1090 10901255	3^	NERV	Headache/ Headache	2	12SEP2020	3/1	2	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain-Left arm	1	19AUG2020	1/3	2	Yes		NA	R (21AUG2020)	N/N
		GENRL	Injection site pain/ left arm injection site pain	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
		MUSC	Mobility decreased/ Decreased mobility of left arm	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Pyrexia/ Low grade fever	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 1 1090 10901259	3^	GENRL	Chills/ Chills	2	05OCT2020	28/2	1	No	O	NA	R (06OCT2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ injection site pain-left arm	1	19AUG2020	1/4	2	Yes		NA/TC	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1090 10901272			Injection site swelling/ Swelling at injection site-left arm	1	19AUG2020	1/3	2	Yes		NA	R (21AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
>55/ C459100 1 1090 10901274	3^	GENRL	Pyrexia/ Fever	1	01SEP2020	1/2	1	Yes		NA/TC	R (02SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	1	01SEP2020	1/2	1	Yes		NA/TC	R (02SEP2020)	N/N
		GENRL	Chills/ Chills	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
			Pyrexia/ Fever	2	21SEP2020	1/1	1	Yes		NA/TC	R (21SEP2020)	N/N
>55/ C459100 1 1090 10901282	3^	GENRL	Chills/ Chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ Injection site pain	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ Low grade fever	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ Generalized muscle aches	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C459100	3^	SKIN	Pruritus/ pruritus, generalized	2	21SEP2020	1/5	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1090 10901284 >55/ C459100 1 1090 10901292	3^	GENRL	Chills/ Chills	2	21SEP2020	1/2	3	Yes		NA	R (22SEP2020)	N/N
			Pain/ Body aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ Headache	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1090 10901296	3^	GENRL	Chills/ Chills	2	21SEP2020	1/2	3	Yes		NA	R (22SEP2020)	N/N
			Injection site pain/ Injection site pain-Left arm	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
			Pain/ Body aches	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
			Pyrexia/ Fever	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
>55/ C459100 1 1090 10901299	3^	GENRL	Pyrexia/ Low grade fever	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100	3^	INJ&P	Arthropod bite/ ant bite, left ankle	1	09SEP2020	8/2	1	No	O	NA	RS (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1090 10901300		IMMUN	Anaphylactic shock/ anaphylactic shock	2	09OCT2020	19/1	4	No	O	NA/TC	R (09OCT2020)	Y/N
>55/ C459100 1 1090 10901306	3^	NERV	Headache/ Headache	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1090 10901307	3^	EAR	Tinnitus/ tinnitus, pulsatile	1	05SEP2020	4/18	1	No	O	NA	R (22SEP2020)	N/N
>55/ C459100 1 1090 10901310	3^	GENRL	Injection site pain/ Injection site pain-Left arm	1	02SEP2020	1/3	2	Yes		NA/TC	R (04SEP2020)	N/N
		GENRL	Chills/ Chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
			Pain/ Body aches	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
			Pyrexia/ Low grade fever	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		NERV	Post herpetic neuralgia/ Post herpetic neuralgia, worsening	2	24SEP2020	2/4	2	Yes		NA	R (27SEP2020)	N/N
>55/ C459100	3^	GENRL	Pyrexia/ Fever	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1090 10901337		MUSC	Musculoskeletal pain/ Left shoulder and neck muscle pain	1	09SEP2020	2/2	1	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C459100 1 1090 10901340	3^	GENRL	Injection site pain/ Left injection site pain	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/Y
		GENRL	Chills/ Chills	2	01OCT2020	2/1	2	Yes		NA	R (01OCT2020)	N/N
			Fatigue/ fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Pyrexia/ fever	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1090 10901342	3^	INJ&P	Fall/ Fall	1	20SEP2020	13/1	2	No	O	NA/TC	R (20SEP2020)	N/N
			Ligament sprain/ Ankle sprain-left	1	20SEP2020	13/6	2	No	O	NA/TC	R (25SEP2020)	N/N
			Ligament sprain/ Arm sprain-right	1	20SEP2020	13/37	2	No	O	NA/TC	R (26OCT2020)	N/N
>55/ C459100 1 1090 10901354	3^	GENRL	Chills/ Chills	2	28SEP2020	1/5	2	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Fatigue	2	28SEP2020	1/5	2	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1090 10901361	3^	GENRL	Injection site pain/ Injection site pain-left arm	2	28SEP2020	1/7	2	Yes		NA/TC	R (04OCT2020)	N/N	
			NERV	Headache/ Headache	2	28SEP2020	1/5	1	Yes		NA/TC	R (02OCT2020)	N/N
			SKIN	Night sweats/ Night sweats	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/Y
			BLOOD	Lymphadenopathy/ Swollen left axillary lymph node	2	29SEP2020	2/6	2	Yes		NA	R (04OCT2020)	N/N
			GENRL	Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
			GENRL	Injection site pain/ Left injection site pain	2	29SEP2020	1/5	2	Yes		NA/TC	R (03OCT2020)	N/Y
>55/ C459100 1 1090 10901376	3^	GENRL	CARD	Tachycardia/ Tachycardia	2	30SEP2020	2/1	1	Yes	NA	R (30SEP2020)	N/N	
			GENRL	Pyrexia/ fever	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
>55/ C459100 1 1090 10901376	3^	GENRL	Injection site pain/ injection site pain	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N	
>55/ C459100 1 1090 10901396	3^	GENRL	Injection site pain/ Injection site pain-left arm	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N	
>55/ C459100	3^	GENRL	Chills/ chills	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1090 10901406			Pain/ Body aches	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C459100 1 1090 10901412	3^	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/4	1	Yes		NA	R (12OCT2020)	N/N
>55/ C459100 1 1090 10901415	3^	NERV	Headache/ Headache	1	30SEP2020	14/21	2	No	O	P/TC	R (20OCT2020)	N/N
>55/ C459100 1 1090 10901420	3^	GENRL	Injection site pain/ Injection site pain-left arm	2	08OCT2020	1/3	2	Yes		NA	R (10OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	09OCT2020	2/6	3	Yes		NA	R (14OCT2020)	N/N
		NERV	Headache/ Headache	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
>55/ C459100 1 1090 10901430	3^	INFEC	Herpes zoster/ shingles, on back (near bra hooks)	1	29SEP2020	9/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1090 10901434	3^	NERV	Headache/ Headache	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1090 10901444	3^	GENRL	Injection site pain/ Injection site soreness	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Musculoskeletal stiffness/ Muscle stiffness-whole right arm	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain, right arm	2	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/Y
		GENRL	Chills/ chills	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
			Pain/ body aches	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C459100 1 1090 10901450	3^	MUSC	Intervertebral disc protrusion/ Bulging disc-lumbar	2	15OCT2020	2/7	2	No	O	NA/TC	R (21OCT2020)	N/N
>55/ C459100 1 1090 10901460	3^	GENRL	Chest pain/ Chest pain	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
			Chills/ chills	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
			Pyrexia/ fever	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1090 10901472	3^	GENRL	Injection site pain/ Injection site pain-left arm	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1090 10901488	3^	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/4	2	Yes		NA/TC	R (10OCT2020)	N/N
>55/ C459100 1 1090 10901493	3^	GENRL	Pain/ Body aches	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N
			Pyrexia/ Fever	2	07NOV2020	2/2	1	Yes		NA/TC	R (08NOV2020)	N/N
>55/ C459100 1 1091 10911001	3^	INJ&P	Arthropod bite/ INSECT BITE OF RIGHT ARM	1	14AUG2020	16/4	1	No	O	NA/TC	R (17AUG2020)	N/N
>55/ C459100 1 1091 10911002	3^	INFEC	Otitis media/ BILATERAL SERIOUS OTITIS MEDIA	1	16AUG2020	18/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1091 10911026	3^	INFEC	Urinary tract infection/ urinary tract infection	2	15SEP2020	1/4	1	No	O	NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1091 10911041	3^	INJ&P	Arthropod bite/ insect bite	2	28AUG2020	3/21	1	No	O	NA/TC	R (17SEP2020)	N/N
>55/ C459100 1 1091 10911050	3^	INJ&P	Fall/ Fall	1	21AUG2020	17/1	1	No	O	NA	R (21AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Skin abrasion/ left knee abrasion	1	21AUG2020	17/8	1	No	O	NA	R (28AUG2020)	N/N
			Arthralgia/ left knee pain	1	21AUG2020	17/8	1	No	O	NA	R (28AUG2020)	N/N
			Flank pain/ left flank pain	1	21AUG2020	17/8	1	No	O	NA	R (28AUG2020)	N/N
>55/ C459100 1 1091 10911055	3^	INFEC	Herpes zoster/ shingles	2	18SEP2020	26/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1091 10911059	3^	INJ&P	Muscle rupture/ Torn left hamstring	2	30AUG2020	4/19	2	No	O	NA/TC	RS (17SEP2020)	N/N
		VASC	Hypotension/ hypotension	2	30AUG2020	4/1	2	No	O	NA/TCN	R (30AUG2020)	N/N
>55/ C459100 1 1091 10911081	3^	GASTR	Diarrhoea/ diarrhea	2	27SEP2020	33/3	1	No	O	NA	R (29SEP2020)	N/N
		INFEC	Otitis media/ otitis media, bilateral	2	30SEP2020	36/3	2	No	O	NA/TC	R (02OCT2020)	N/N
			Sinusitis/ sinusitis	2	30SEP2020	36/3	2	No	O	NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1091 10911112	3^	GENRL	Injection site pain/ injection site pain	2	19SEP2020	19/C	1	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1091 10911127	3^	MUSC	Pain in extremity/ left arm pain	2	15SEP2020	2/5	1	Yes		NA	R (19SEP2020)	N/N
		MUSC	Myalgia/ myalgia	2	16SEP2020	3/1	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1091 10911170	3^	BLOOD	Lymphadenopathy/ enlarged left axillary lymph node	1	03SEP2020	10/28	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1091 10911191	3^	MUSC	Myalgia/ generalized myalgias	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1091 10911193	3^	MUSC	Pain in extremity/ left arm pain	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 1 1091 10911195	3^	GENRL	Pain/ generalized body aches	1	29AUG2020	2/7	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ injection site pain	2	15SEP2020	1/3	1	Yes		NA	RS (17SEP2020)	N/N
			Pain/ generalized body aches	2	15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1091 10911205	3^	GENRL	Injection site pain/ soreness at injection	1	03SEP2020	4/3	1	Yes		NA	R (05SEP2020)	N/N
>55/ C459100 1 1091 10911209	3^	GENRL	Pyrexia/ fever	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1091 10911211	3^	GENRL	Injection site pain/ injection site soreness	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
>55/ C459100 1 1091 10911213	3^	GENRL	Injection site pain/ injection site soreness	1	02SEP2020	2/8	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Injection site erythema/ injection site redness	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ injection site pain	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1091 10911222	3^	GENRL	Injection site pain/ Soreness at injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ Injection site pain	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1091 10911230	3^	MUSC	Myalgia/ Myalgia	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ Left arm pain at injection site	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 1 1091 10911231	3^	MUSC	Injection site pain/ Left arm pain at injection site	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		MUSC	Myalgia/ myalgia	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 1 1091 10911234	3^		Pain in extremity/ left arm pain	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		MUSC	Myalgia/ generalized myalgia	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C459100	3^	GASTR	Diarrhoea/ Diarrhea	2	26SEP2020	3/1	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Chills/ chills (without fever)	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1091 10911242			Fatigue/ fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1091 10911243	3^	GENRL	Chills/ chills (without fever)	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N
>55/ C459100 1 1091 10911247	3^	GASTR	Dental caries/ dental cavity	1	17SEP2020	15/1	1	No	O	NA	R (17SEP2020)	N/N
		INJ&P	Arthropod sting/ Itching due to Beestings	1	17SEP2020	15/5	2	No	O	NA/TC	R (21SEP2020)	N/N
			Arthropod sting/ Swelling due to Beestings	1	17SEP2020	15/5	1	No	O	NA/TC	R (21SEP2020)	N/N
>55/ C459100 1 1091 10911249	3^	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ R arm injection site pain	2	22SEP2020	1/7	1	Yes		NA	R (28SEP2020)	N/N
		GENRL	Chills/ Chills	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		EAR	Vertigo positional/ Benign Paroxysmal Positional Vertigo	2	17OCT2020	26/4	2	No	O	NA/TC	R (20OCT2020)	N/N
>55/ C459100 11091 10911258	3^	INFECTION	Otitis media bacterial/ L ear bacterial otitis media (medical history)	1	14SEP2020	6/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 11091 10911268	3^	GENRL	Injection site pain/ Injection Site Pain	2	28SEP2020	1/5	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Malaise/ Malaise	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 11091 10911269	3^	GENRL	Fatigue/ fatigue	1	10SEP2020	2/8	1	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ Pain at Injection site	1	10SEP2020	2/8	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ headache	1	10SEP2020	2/8	1	No	O	NA/TC	R (17SEP2020)	N/N
		RESP	Rhinalgia/ Right Nostril Pain	1	10SEP2020	2/8	1	No	O	NA	R (17SEP2020)	N/N
		RESP	Throat irritation/ throat irritation	1	12SEP2020	4/6	1	No	O	NA	R (17SEP2020)	N/N
		GASTR	Toothache/ Toothache, Unspecified Right Side	1	19SEP2020	11/8	1	No	O	NA/TC	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1091 10911272	3^	INFEC	Tooth infection/ Infection of tooth	1	19SEP2020	11/8	1	No	O	NA/TC	R (26SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/11	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	30SEP2020	2/8	1	Yes		NA	R (07OCT2020)	N/N
		NERV	Headache/ Headaches	2	30SEP2020	2/8	1	Yes		NA/TC	R (07OCT2020)	N/N
		GENRL	Injection site pain/ Mild pain right arm at injection site	1	10SEP2020	1/8	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Mild Pain R Arm at Injection Site	2	29SEP2020	1/4	1	Yes		NA	R (02OCT2020)	N/N
		SKIN	Angioedema/ periorbital angioedema	1	11SEP2020	2/3	1	No	O	NA/TC	R (13SEP2020)	N/N
>55/ C459100 1 1091 10911292	3^	SKIN	Angioedema/ periorbital angioedema	1	27SEP2020	18/2	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	18SEP2020	8/C	2	No	O	NA	RG	N/N
			Malaise/ malaise	1	18SEP2020	8/C	1	No	O	NA	RG	N/N
		METAB	Decreased appetite/ loss of appetite	1	18SEP2020	8/C	1	No	O	NA	RG	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11091 10911294	3^	NERV	Headache/ headache	2	05OCT2020	1/C	1	Yes		NA/TC	N	N/N
		GENRL	Fatigue/ fatigue	2	06OCT2020	2/C	1	Yes		NA	N	N/N
			Injection site pain/ injection site pain	2	06OCT2020	2/C	1	Yes		NA	N	N/N
			Pyrexia/ fever	2	06OCT2020	2/C	1	Yes		NA	N	N/N
		MUSC	Arthralgia/ arthralgias	2	06OCT2020	2/C	1	Yes		NA	N	N/N
>55/ C459100 11091 10911318	3^	GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	1/4	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 11091 10911335	3^	GENRL	Chills/ chills	2	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N
		NERV	Headache/ headache	2	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 11091 10911337	3^	GENRL	Fatigue/ fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1091 10911345	3^	GENRL	Pyrexia/ fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
			NERV	Headache/ headache	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
			Injection site pain/ injection site pain	2	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N	
			GENRL	Chills/ chills	2	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
			Fatigue/ fatigue	2	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N	
>55/ C459100 1 1091 10911354	3^	GENRL	Injection site pain/ Injection Site Pain	1	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
>55/ C459100 1 1092 10921006	3^	RESP	Paranasal sinus discomfort/ sinus pressure	1	19AUG2020	1/3	1	Yes		NA/TC	R (21AUG2020)	N/N	
>55/ C459100 1 1092 10921007	3^	GASTR	Diarrhoea/ Diarrhea	2	09SEP2020	2/1	1	No	O	NA	R (09SEP2020)	N/N	
		GENRL	Chills/ Chills	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	
		MUSC	Myalgia/ myalgia	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1092 10921010	3^	INFEC	Vulvovaginitis/ Vulvovaginitis	1	03SEP2020	16/40	1	No	O	NA/TC	R (12OCT2020)	N/N
>55/ C459100 1 1092 10921015	3^	CARD	Atrial fibrillation/ Arrhythmia atrial fibrillation	1	26AUG2020	8/2	2	No	O	NA/TC	R (27AUG2020)	Y/N
		INV	Troponin increased/ Elevated troponin	1	26AUG2020	8/1	1	No	O	NA	R (26AUG2020)	N/N
>55/ C459100 1 1092 10921040	3^	EAR	Vertigo positional/ intermittent positional vertigo	1	05SEP2020	16/7	1	No	O	NA/TC	R (11SEP2020)	N/N
		MUSC	Back pain/ constant right low back pain	1	05SEP2020	16/5	1	No	O	NA/TC	R (09SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Lethargy/ Lethargy	2	11SEP2020	3/4	1	Yes		NA	R (14SEP2020)	N/N
		INFEC	Sinusitis/ sinus infection	2	15SEP2020	7/6	1	No	O	NA/TC	R (20SEP2020)	N/N
		RESP	Sinus congestion/ sinus congestion	2	15SEP2020	7/6	1	No	O	NA/TC	R (20SEP2020)	N/N
>55/ C459100 1 1092 10921046	3^	GENRL	Pyrexia/ Fever	1	25AUG2020	2/2	1	Yes		NA/TC	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1092 10921049	3^	RESP	Asthma/ Asthma exacerbation	2	21SEP2020	8/9	1	No	O	NA/TC	R (29SEP2020)	N/N
		NERV	Headache/ Headache	1	24AUG2020	1/3	1	Yes		NA/TC	R (26AUG2020)	N/N
		GENRL	Pyrexia/ Fever	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
		MUSC	Myalgia/ generalized myalgia	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
		GENRL	Chills/ Chills	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
			Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1092 10921057	3^	NERV	Headache/ Headache	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		INJ&P	Animal bite/ dog bite	2	26SEP2020	12/1	1	No	O	NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1092 10921062	3^	RESP	Respiratory tract congestion/ Chest Congestion	2	18SEP2020	5/10	1	No	O	NA/TC	R (27SEP2020)	N/N
			Upper respiratory tract congestion/ Head congestion	2	18SEP2020	5/10	1	No	O	NA/TC	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1092 10921072	3^	INFEC	Laryngitis/ Laryngitis	2	28SEP2020	15/14	1	No	O	NA/TC	R (11OCT2020)	N/N
		RESP	Asthma/ Asthma exacerbation	2	28SEP2020	15/14	1	No	O	NA/TC	R (11OCT2020)	N/N
		GENRL	Chills/ chills	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
		NERV	Dizziness/ continuous lightheadedness	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
		NERV	Headache/ generalized dull headache	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
>55/ C459100 1 1092 10921089	3^	GENRL	Lethargy/ continuous lethargy	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
		GENRL	Pain/ generalized achiness	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1092 10921094	3^	NERV	Pyrexia/ fever	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1092 10921094	3^	NERV	Lethargy/ lethargy	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 1 1092 10921108	3^	SKIN	Rash pruritic/ pruritic rash	1	06SEP2020	3/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1092 10921115	3^	INFEC	Skin infection/ skin infection left elbow	1	03SEP2020	4/4	1	No	O	NA/TC	R (06SEP2020)	N/N
		INFEC	Paronychia/ paronychia right middle finger	2	10OCT2020	20/8	1	No	O	NA/TC	R (17OCT2020)	N/N
>55/ C459100 1 1092 10921116	3^	INJ&P	Mouth injury/ laceration of mouth	1	07SEP2020	8/11	2	No	O	NA/TC	R (17SEP2020)	N/N
			Skin laceration/ laceration left hand	1	07SEP2020	8/11	2	No	O	NA/TC	R (17SEP2020)	N/N
			Skin laceration/ laceration right elbow	1	07SEP2020	8/11	2	No	O	NA/TC	R (17SEP2020)	N/N
>55/ C459100 1 1092 10921120	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	2	06OCT2020	15/5	1	No	O	NA/TC	R (10OCT2020)	N/N
>55/ C459100 1 1092 10921123	3^	EYE	Eye swelling/ Swelling of eyes	1	17SEP2020	17/2	2	No	CD	NA/TC	R (18SEP2020)	N/N
		GASTR	Lip swelling/ Swelling of lip	1	17SEP2020	17/2	2	No	CD	NA/TC	R (18SEP2020)	N/N
		SKIN	Urticaria/ Hives (Urticaria)	1	17SEP2020	17/2	2	No	CD	NA/TC	R (18SEP2020)	N/N
		GASTR	Abdominal pain upper/ Epigastric Pain	1	07OCT2020	37/2	3	No	O	NA/TC	R (08OCT2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Chronic gastritis/ Chronic Focally Active Gastritis	1	07OCT2020	37/C	2	No	O	NA	N	N/N
>55/ C459100 1 1092 10921136	3^	GENRL	Injection site induration/ induration at injection site	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/Y
			Injection site pain/ left arm injection site pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/Y
		NERV	Headache/ headache unknown type	1	02SEP2020	2/2	2	Yes		NA/TC	R (03SEP2020)	N/N
		NERV	Lethargy/ lethargy	1	03SEP2020	3/3	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ pain in arm at injection site	1	20SEP2020	20/4	1	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ headache	2	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
			Lethargy/ lethargy	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1092 10921137	3^	NERV	Lethargy/ lethargy	2	23SEP2020	1/4	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1092 10921140	3^	GENRL	Injection site pain/ left arm muscle pain at injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100	3^	GASTR	Nausea/ nausea	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1092 10921152		GENRL	Chills/ chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		SKIN	Hyperhidrosis/ sweating	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		EAR	Vertigo/ vertigo	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		GASTR	Retching/ dry heaves	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		GENRL	Malaise/ malaise	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		INV	Respiratory rate increased/ increased respiratory rate	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1092 10921155	3^	GASTR	Diarrhoea/ Diarrhea	1	09SEP2020	7/4	1	No	O	NA	R (12SEP2020)	N/N
		GENRL	Pyrexia/ Fever	1	09SEP2020	7/4	1	No	O	NA	R (12SEP2020)	N/N
		GASTR	Diarrhoea/ diarrhea	2	11OCT2020	4/2	1	Yes		NA	R (12OCT2020)	N/N
		NERV	Headache/ headache	2	11OCT2020	4/2	1	Yes		NA	R (12OCT2020)	N/N
>55/ C459100	3^	MUSC	Back pain/ lower back pain	2	25OCT2020	26/8	1	No	O	NA/TC	R (01NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1092 10921171 >55/ C459100	3^	NERV	Headache/ headache	1	13SEP2020	5/3	1	No	O	NA/TC	R (15SEP2020)	N/N
1 1092 10921172 >55/ C459100	3^	GENRL	Injection site pain/ Injection site tenderness	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
1 1092 10921180		INJ&P	Contusion/ contusion to head	1	25SEP2020	16/1	2	No	O	NA/TC	R (25SEP2020)	N/N
			Fall/ fall	1	25SEP2020	16/1	2	No	O	NA/TC	R (25SEP2020)	N/N
			Skin laceration/ laceration left elbow	1	25SEP2020	16/4	2	No	O	NA/TC	R (28SEP2020)	N/N
>55/ C459100 1 1092 10921187	3^	CARD	Cardiac failure congestive/ Congestive heart failure	1	01OCT2020	17/3	2	No	O	NA/TC	R (03OCT2020)	Y/N
>55/ C459100 1 1092 10921194	3^	INJ&P	Head injury/ hit head on steering wheel	2	02NOV2020	20/1	1	No	O	NA	R (02NOV2020)	N/N
			Road traffic accident/ motor vehicle accident while subject was driving	2	02NOV2020	20/1	1	No	O	NA	R (02NOV2020)	N/N
		NERV	Headache/ headache	2	02NOV2020	20/2	2	No	O	NA	R (03NOV2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1092 10921196	3^	GENRL	Injection site pain/ Injection site tenderness	1	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Tenderness	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
>55/ C459100 1 1092 10921212	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	1	27OCT2020	21/11	1	No	O	NA/TC	R (06NOV2020)	N/N
>55/ C459100 1 1093 10931005	3^	INFEC	Otitis media/ BILATERAL INNER OTITIS MEDIA	1	03SEP2020	20/18	1	No	O	NA/TC	R (20SEP2020)	N/N
>55/ C459100 1 1093 10931023	3^	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	21AUG2020	3/33	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	09SEP2020	1/17	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	1/22	1	Yes		NA/TC	R (30SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		SKIN	Hyperhidrosis/ SWEATING	2	09SEP2020	1/17	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11093 10931122	3^	RESP	Asthma/ ASTHMA EXACERBATION	2	16OCT2020	17/5	2	No	O	NA/TCN	R (20OCT2020)	N/N
>55/ C459100 11094 10941009	3^	SKIN	Erythema/ Redness left and right arm	2	23SEP2020	23/1	2	No	O	NA	R (23SEP2020)	N/N
		INFEC	Urinary tract infection/ urinary tract infection	2	28SEP2020	28/7	2	No	O	NA/TC	R (04OCT2020)	N/N
>55/ C459100 11094 10941014	3^	CARD	Palpitations/ palpitation	2	03OCT2020	32/C	1	No	O	NA	N	N/N
>55/ C459100 11094 10941072	3^	NEOPL	Breast cancer/ Right breast cancer	1	10SEP2020	11/C	3	No	O	NA	N	N/N
>55/ C459100 11094 10941073	3^	MUSC	Pain in extremity/ Left arm musculoskeletal pain	1	01SEP2020	2/C	2	Yes		NA/TC	N	N/N
>55/ C459100 11094 10941085	3^	PSYCH	Dysphemia/ stutter	2	01OCT2020	4/C	1	No	O	NA	N	N/N
>55/ C459100 11094 10941096	3^	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	2	30SEP2020	3/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		METAB	Vitamin B12 deficiency/ Vitamin B12 DEFICIENCY	2	30SEP2020	3/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1094 10941103	3^	GENRL	Asthenia/ General Weakness	1	07SEP2020	1/16	2	Yes		NA	R (22SEP2020)	N/N
		GASTR	Nausea/ Nausea	1	08SEP2020	2/4	2	No	O	NA	R (11SEP2020)	N/N
		NERV	Dizziness/ Dizziness	1	08SEP2020	2/15	2	No	O	NA	R (22SEP2020)	N/N
		INJ&P	Skin abrasion/ Left forearm abrasion	2	24OCT2020	27/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1094 10941110	3^	CARD	Palpitations/ Palpitations	1	13SEP2020	6/2	1	No	O	NA	R (14SEP2020)	N/N
>55/ C459100 1 1094 10941112	3^	MUSC	Arthralgia/ joint pain	2	30SEP2020	2/5	2	No	O	NA/TC	R (04OCT2020)	N/N
>55/ C459100 1 1095 10951015	3^	MUSC	Neck pain/ NECK PAIN	2	29AUG2020	9/3	1	No	O	NA/TC	R (31AUG2020)	N/N
>55/ C459100 1 1095 10951016	3^	GENRL	Injection site haemorrhage/ left arm injection site ecchymosis	1	31JUL2020	1/15	1	Yes		NA	R (14AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1095 10951032	3^	INJ&P	Limb injury/ right shoulder pain secondary to injury	2	09SEP2020	17/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1095 10951043	3^	EYE	Chalazion/ Chalazion of lower right eye	1	23AUG2020	20/6	1	No	O	NA	R (28AUG2020)	N/N
>55/ C459100 1 1095 10951048	3^	INJ&P	Corneal abrasion/ Right Corneal Abrasion	1	20AUG2020	17/2	1	No	O	NA	R (21AUG2020)	N/N
>55/ C459100 1 1095 10951052	3^	INJ&P	Ankle fracture/ right medial malleolus fracture	2	07SEP2020	14/C	3	No	O	NA/TC	RG	N/N
			Foot fracture/ bilateral calcaneus fracture	2	07SEP2020	14/C	3	No	O	NA/TC/TCN	RG	N/N
>55/ C459100 1 1095 10951078	3^	EYE	Dacryostenosis acquired/ right lacrimal duct obstruction	1	15AUG2020	10/C	1	No	O	NA/TC	N	N/N
		INFEC	Gastroenteritis/ Mild gastroenteritis	1	24AUG2020	19/4	1	No	O	NA	R (27AUG2020)	N/N
>55/ C459100 1 1095 10951088	3^	INJ&P	Fall/ FALL	1	13AUG2020	8/1	1	No	O	NA	R (13AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Skin abrasion/ superficial abrasions on anterior chest	1	13AUG2020	8/18	1	No	O	NA/TC	R (30AUG2020)	N/N
			Skin laceration/ Superficial laceration to posterior head	1	13AUG2020	8/18	1	No	O	NA	R (30AUG2020)	N/N
		VASC	Haematoma/ Hematoma right anterior chest	1	13AUG2020	8/18	1	No	O	NA/TC	R (30AUG2020)	N/N
>55/ C459100 1 1095 10951098	3^	GENRL	Injection site erythema/ Erythema to injection site left arm	2	29AUG2020	2/7	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 1 1095 10951101	3^	RESP	Pulmonary embolism/ Pulmonary Embolism	2	30OCT2020	64/9	3	No	O	NA/TC	R (07NOV2020)	Y/N
>55/ C459100 1 1095 10951102	3^	MUSC	Joint effusion/ Left knee effusion	1	13AUG2020	7/C	1	Yes		NA	RG	N/N
>55/ C459100 1 1095 10951107	3^	METAB	Hypoglycaemia/ Hypoglycemia	1	12AUG2020	6/1	1	No	O	NA/TCN	R (12AUG2020)	N/N
		NERV	Dizziness/ Dizziness, secondary to Clonidine reaction	2	31AUG2020	5/3	2	No	O	NA	R (02SEP2020)	Y/N
		CARD	Tachyarrhythmia/ Suspected tachy-arrythmia	2	08SEP2020	13/15	3	No	O	NA/TC	R (22SEP2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1095 10951113	3^	GENRL	Injection site pain/ injection site pain	2	10SEP2020	2/4	1	Yes		NA/TC	R (13SEP2020)	N/N
>55/ C459100 1 1095 10951118	3^	GENRL	Fatigue/ Fatigue	2	13SEP2020	3/2	1	Yes		NA	R (14SEP2020)	N/N
		INV	Body temperature increased/ Elevated temperature	2	13SEP2020	3/2	1	Yes		NA	R (14SEP2020)	N/N
>55/ C459100 1 1095 10951123	3^	GENRL	Injection site pain/ injection site pain	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/Y
		PSYCH	Depression/ worsening of Depression	2	17SEP2020	4/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1095 10951127	3^	GENRL	Injection site pain/ Injection site pain Left arm	1	25AUG2020	1/2	1	Yes		NA/TC	R (26AUG2020)	N/N
>55/ C459100 1 1095 10951130	3^	MUSC	Back pain/ Mechanical low back pain	2	13OCT2020	28/1	1	No	O	NA/TC	R (13OCT2020)	N/N
>55/ C459100 1 1095 10951133	3^	GENRL	Injection site pain/ injection site pain left arm	1	26AUG2020	2/3	1	Yes		NA/TC	R (28AUG2020)	N/N
		MUSC	Muscle spasms/ muscle spasm bilateral thighs	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1095 10951136	3^	INJ&P	Post concussion syndrome/ Post concussion headache	1	04SEP2020	10/10	1	No	O	NA/TC	R (13SEP2020)	N/N
>55/ C459100 1 1095 10951140	3^	GENRL	Injection site pain/ injection site pain left arm	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Injection site pain/ Pain at injection site, left arm	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1095 10951151	3^	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
			Injection site swelling/ Injection site swelling	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1095 10951162	3^	GENRL	Injection site pain/ injection site pain left arm	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
		INV	Body temperature increased/ Elevated temperature	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1095 10951164	3^	GENRL	Injection site pain/ Injection site reaction left arm- myalgia	1	30AUG2020	2/1	1	Yes		NA/TC	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1095 10951180	3^	GENRL	Injection site pain/ Injection site reaction-myalgia	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		INV	Body temperature increased/ elevated body temperature	2	18SEP2020	2/3	1	Yes		NA/TC	R (20SEP2020)	N/N
		METAB	Decreased appetite/ Anorexia	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		MUSC	Musculoskeletal chest pain/ Chest Wall tightness	2	18SEP2020	2/3	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ post vaccination myalgia	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N	
	3^	NERV	Dizziness/ Dizziness	2	05NOV2020	45/2	1	No	O	NA	R (06NOV2020)	Y/N
		MUSC	Myalgia/ Post injection myalgia	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain right arm	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	>55/ C459100 1 1095 10951204	3^	GENRL	Injection site pain/ injection site pain right arm	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)
GENRL			Injection site pain/ Injection site pain right arm	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NEOPL	Bladder cancer/ Bladder Cancer	2	02NOV2020	43/C	3	No	O	NA	N	Y/N
>55/ C459100 1 1095 10951206	3^	MUSC	Osteoporosis/ osteoporosis right hip	1	22SEP2020	21/C	2	No	O	NA	N	N/N
>55/ C459100 1 1095 10951209	3^	METAB	Hypokalaemia/ Hypokalemia secondary to diuretic use	1	17SEP2020	16/C	1	No	CD	NA/TC	RG	N/N
>55/ C459100 1 1095 10951211	3^	GENRL	Fatigue/ Post vaccination fatigue	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
			Injection site pain/ injection site pain right arm	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
		NERV	Headache/ headache	1	02SEP2020	1/4	1	Yes		NA/TC	R (05SEP2020)	N/N
		GENRL	Injection site pruritus/ pruritis at injection site right arm	1	12SEP2020	11/2	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Malaise/ malaise post vaccination	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Fatigue/ Fatigue post vaccination	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Vaccination site pain/ injection site pain post vaccination right arm	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100	3^	INJ&P	Vaccination complication/ post vaccination malaise	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1095 10951212		INV	Body temperature increased/ elevated temperature	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		RESP	Pleurisy/ Pleuritis	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1095 10951213	3^	GASTR	Nausea/ Nausea post vaccine #2	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Pyrexia/ Fever post vaccination #2	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgia post vaccine #2	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ Headache Post Vaccination #2	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1095 10951219	3^	INV	Body temperature increased/ Elevated Temperature	2	04NOV2020	42/2	1	No	O	NA/TC	R (05NOV2020)	N/N
>55/ C459100 1 1095 10951224	3^	GENRL	Pyrexia/ Fever	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100	3^	NERV	Headache/ Headache	1	11SEP2020	8/2	1	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1095 10951226												
>55/ C459100 1 1095 10951227	3^	GENRL	Injection site pain/ injection site myalgia left arm	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
>55/ C459100 1 1095 10951228	3^	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		UNC	SHORTNESS OF BREATH@@/ shortness of breath	2	13NOV2020	51/C	2	No	O	NA/TC	N	Y/N
>55/ C459100 1 1095 10951238	3^	GASTR	Nausea/ nausea	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
			Vomiting/ Vomiting	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1095 10951239	3^	GENRL	Injection site pain/ Injection site pain	1	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C459100 1 1095 10951242	3^	GENRL	Fatigue/ Fatigue post vaccine	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ Headache post vaccine #1	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache post-vaccination #2	2	16OCT2020	1/3	1	Yes		NA/TC	R (18OCT2020)	N/N
		GENRL	Malaise/ General malaise post-vaccination #2	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
		MUSC	Back pain/ Myalgias (back muscles) post-vaccination #2	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
>55/ C459100 1 1095 10951252	3^	GENRL	Injection site pain/ Injection site soreness	1	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
>55/ C459100 1 1095 10951263	3^	GASTR	Diarrhoea/ diarrhea	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
>55/ C459100 1 1095 10951264	3^	GENRL	Injection site pain/ Pain at injection site right arm	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1096 10961002	3^	GASTR	Diarrhoea/ Diarrhea	2	06SEP2020	3/5	3	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Intermittent headaches	2	18SEP2020	15/C	1	Yes		NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1096 10961020	3^	GENRL	Injection site erythema/ Erythema around injection vaccine	2	21SEP2020	18/3	1	No	O	NA	R (23SEP2020)	N/N
			Injection site pain/ Soreness around the injection site	2	21SEP2020	18/3	1	No	O	NA	R (23SEP2020)	N/N
>55/ C459100 1 1096 10961044	3^	INV	Hepatic enzyme increased/ Elevated Liver Enzymes	2	21SEP2020	12/C	3	No	O	NA	N	Y/N
>55/ C459100 1 1096 10961047	3^	GENRL	Chills/ Chills	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
		SKIN	Dermal cyst/ Left leg cyst (sebaceous)	2	14SEP2020	7/C	1	No	O	NA	N	N/N
>55/ C459100 1 1096 10961065	3^	IMMUN	Seasonal allergy/ Seasonal allergies	2	22SEP2020	14/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1096 10961070	3^	GENRL	Chills/ chills	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ fever	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Lethargy/ lethargic	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1096 10961079	3^	EAR	Vertigo/ Vertigo	2	12SEP2020	3/41	1	Yes		NA	R (22OCT2020)	N/N
		GASTR	Dyspepsia/ Heart burn	2	12SEP2020	3/19	1	Yes		NA/TC	R (30SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1096 10961092	3^	INFEC	Pyrexia/ Fever	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
			Sinusitis/ Sinus infection	2	22SEP2020	13/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1096 10961094	3^	INJ&P	Skin laceration/ right hand laceration	1	05SEP2020	15/21	1	No	O	NA/TC	R (25SEP2020)	N/N
>55/ C459100 1 1096 10961117	3^	INFEC	Trichomoniasis/ trichomoniasis	1	10SEP2020	20/23	1	No	O	NA/TC	R (02OCT2020)	N/N
		NERV	Dizziness/ DIZZINESS	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
			Nausea/ NAUSEA	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ WORSENING HEADACHES	1	25AUG2020	2/4	1	Yes		NA	R (28AUG2020)	N/N
>55/ C459100 1 1096 10961124	3^	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C459100 1 1096 10961129	3^	GENRL	Chills/ Chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
			Injection site erythema/ Injection site redness	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
			Injection site swelling/ Injection site swelling	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	2	16SEP2020	2/3	1	Yes		NA/TC	R (18SEP2020)	N/N
		INFEC	Sinusitis/ Sinus infections	2	04OCT2020	20/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1096 10961133	3^	MUSC	Arthralgia/ left knee pain	1	03SEP2020	10/C	2	No	O	NA/TC	N	N/N
		INJ&P	Meniscus injury/ torn meniscus left knee	1	15SEP2020	22/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1096 10961156	3^	MUSC	Myalgia/ Muscle pain	2	20SEP2020	4/2	1	No	O	NA	R (21SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1096 10961159	3^	GENRL	Injection site pain/ Soreness at injection site*		28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
>55/ C459100 1 1096 10961160	3^	GASTR	Abdominal pain/ Abdominal pain	1	11SEP2020	15/7	2	No	O	NA	R (17SEP2020)	N/N
		RESP	Nasal congestion/ Nasal congestion	1	17SEP2020	21/C	2	No	O	NA	N	N/N
			Oropharyngeal pain/ Sore throat	1	17SEP2020	21/C	1	No	O	NA	N	N/N
>55/ C459100 1 1096 10961164	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1096 10961166	3^	GENRL	Pain/ generalized body aches	2	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1096 10961167	3^	GENRL	Injection site pain/ injection site tenderness	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Chills/ chills	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1096 10961182	3^	GENRL	Pain/ GENERALIZED BODY ACHES	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
			Pyrexia/ FEVER	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site erythema/ Redness around injection site	1	29AUG2020	1/1	1	Yes		NA	R (29AUG2020)	N/N
			Injection site pain/ Pain around the injection site	1	29AUG2020	1/1	2	Yes		NA	R (29AUG2020)	N/N
		GASTR	Glossodynia/ tongue soreness	2	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Pain/ generalized body aches	2	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
		MUSC	Arthralgia/ LEFT SIDE HIP PAIN	2	25SEP2020	7/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1096 10961184	3^	MUSC	Back pain/ LOWER LEFT BACK PAIN	2	01OCT2020	13/9	2	No	O	NA/TC	R (09OCT2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE SORENESS	2	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Pyrexia/ FEVER	2	20SEP2020	2/2	2	Yes		NA	R (21SEP2020)	N/N
		MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ HEADACHE	2	20SEP2020	2/2	2	Yes		NA	R (21SEP2020)	N/N
>55/ C459100 1 1096 10961191	3^	GENRL	Injection site pain/ INJECTION SITE TENDERNESS IN LEFT ARM	1	30AUG2020	2/4	1	Yes		NA	R (02SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Injection site tenderness in left arm.	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1096 10961192	3^	GENRL	Injection site pain/ injection site soreness	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1096 10961201	3^	GENRL	Injection site pain/ Injection site soreness	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1096 10961202	3^	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/16	1	No	O	NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		BLOOD	Anaemia/ anemia	2	02NOV2020	35/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1096 10961204	3^	GENRL	Injection site pain/ injection site soreness	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1096 10961232	3^	GENRL	Injection site pruritus/ itchy around site injection	2	22SEP2020	1/8	1	Yes		NA	R (29SEP2020)	N/N
>55/ C459100 1 1096 10961241	3^	GENRL	Chills/ chills	2	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
			Fatigue/ Fatigue	2	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1096 10961248	3^	GENRL	Injection site erythema/ INJECTION SITE REDNESS	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
			Injection site pain/ INJECTION SITE TENDERNESS	1	04SEP2020	1/3	2	Yes		NA/TC	R (06SEP2020)	N/N
			Injection site swelling/ INJECTION SITE SWELLING	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		INV	Body temperature increased/ INCREASED BODY TEMPERATURE	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ INJECTION SITE TENDERNESS	2	25SEP2020	1/5	2	Yes		NA	R (29SEP2020)	N/N
			Pain/ GENERALIZED BODY ACHES	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
			Pyrexia/ FEVER	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1096 10961252	3^	GENRL	Injection site pain/ Injection site soreness	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N
		GENRL	Injection site erythema/ Injection site redness	1	05SEP2020	2/5	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 1 1096 10961260	3^	GENRL	Injection site pain/ Injection site soreness	2	26SEP2020	1/4	2	Yes		NA	R (29SEP2020)	N/N
		INJ&P	Joint injury/ Left knee injury	2	26SEP2020	1/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1096 10961270	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS IN LEFT ARM	1	06SEP2020	2/2	2	Yes		NA	R (07SEP2020)	N/N
			Pain/ GENERALIZED BODY ACHES	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
			Pyrexia/ FEVER	1	06SEP2020	2/2	2	Yes		NA	R (07SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1096 10961273	3^	INV	Body temperature increased/ INCREASED BODY TEMPERATURE	1	06SEP2020	2/1	1	Yes		NA/TC	R (06SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
		SKIN	Rash/ Rash, breasts	1	06SEP2020	2/C	1	Yes		NA	N	N/N
		GENRL	Chills/ Chills	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
			Fatigue/ Fatigue	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/Y
			Injection site pain/ INJECTION SITE SORENESS IN LEFT ARM	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N
		MUSC	Myalgia/ Generalized muscle aches	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
			Injection site pain/ Injection site pain	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Injection site swelling/ Injection site swelling	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1096 10961281	3^	GENRL	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
			Chills/ Chills	2	26SEP2020	3/1	2	Yes		NA	R (26SEP2020)	N/N	
			SKIN Hyperhidrosis/ Sweating	2	26SEP2020	3/1	1	Yes			NA	R (26SEP2020)	N/N
			NERV Headache/ Intermittent Headaches	2	28SEP2020	5/13	1	Yes			NA/TC	R (10OCT2020)	N/N
>55/ C459100 1 1096 10961283	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N	
			INFEC Hordeolum/ left eye stye	2	07OCT2020	13/C	1	No	O		NA/TC	N	N/N
>55/ C459100 1 1096 10961285	3^	NERV	Headache/ Headaches	1	06SEP2020	2/1	1	Yes		NA/TC	R (06SEP2020)	N/N	
>55/ C459100 1 1096 10961285	3^	GENRL	Injection site pain/ Injection site soreness*		05SEP2020	1/2	2	Yes		NA/TC	R (06SEP2020)	N/N	
>55/ C459100 1 1096 10961295	3^	GENRL	Fatigue/ fatigue	2	21OCT2020	23/2	1	No	O	NA/TC	R (22OCT2020)	N/N	
			Pain/ generalized body aches due to shingrix vaccine	2	21OCT2020	23/2	1	No	O	NA/TC	R (22OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1096 10961300	3^	GENRL	Injection site pain/ Injection site soreness	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness	2	29SEP2020	2/3	2	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1096 10961308	3^	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		INV	Body temperature increased/ Increased body temperature	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		MUSC	Myalgia/ Generalized muscle aches	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1096 10961329	3^	NERV	Headache/ Headaches	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1096 10961332	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1096 10961334	3^	INJ&P	Bone contusion/ injury to right side rib (bruised)	1	28SEP2020	14/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1096 10961337	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Chronic obstructive pulmonary disease/ exacerbation of chronic obstructive pulmonary disease	2	24OCT2020	19/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1096 10961346	3^	RESP	Dry throat/ dry throat	1	17SEP2020	2/1	1	No	O	NA	R (17SEP2020)	N/N
>55/ C459100 1 1096 10961356	3^	NERV	Presyncope/ PRESYNCOPE	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/Y
		GENRL	Fatigue/ Fatigue	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ Injection site soreness	1	18SEP2020	2/3	2	Yes		NA	R (20SEP2020)	N/N
		GENRL	Injection site pain/ Injection site tenderness	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/Y
>55/ C459100 1 1096 10961364	3^	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1097 10971011	3^	INFEC	Pneumonia/ Pneumonia	2	20SEP2020	12/16	3	No	O	NA/TC	R (05OCT2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1097 10971017	3^	INFEC	Urinary tract infection/ urinary tract infection	2	19SEP2020	5/44	3	No	O	NA/TC	R (01NOV2020)	N/N
		NERV	Encephalopathy/ Acute encephalopathy	2	18OCT2020	34/C	3	No	O	NA/TC	RG	Y/N
		SURG	Hospitalisation/ Hospitalization not otherwise specified.	2	13NOV2020	60/C	3	No	O	NA	N	Y/N
>55/ C459100 1 1097 10971025	3^	CARD	Acute myocardial infarction/ Non-STEMI	2	15SEP2020	2/1	3	No	O	NA/TC/TCN	R (15SEP2020)	Y/N
>55/ C459100 1 1097 10971060	3^	INJ&P	Fall/ Fall	1	11SEP2020	15/1	2	No	O	NA/TC	R (11SEP2020)	N/N
			Ligament sprain/ Sprained Ankle	1	11SEP2020	15/8	2	No	O	NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1097 10971061	3^	NERV	Uraemic encephalopathy/ Uremic encephalopathy	2	22OCT2020	36/4	3	No	O	NA/TC	RS (25OCT2020)	Y/N
		RENAL	Acute kidney injury/ Acute kidney injury	2	22OCT2020	36/4	3	No	CD	NA/TC	RS (25OCT2020)	Y/N
>55/ C459100 1 1097 10971084	3^	INFEC	Pneumonia/ Pneumonia	2	07OCT2020	15/C	3	No	O	NA/TC/TCN	RG	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1097 10971115	3^	GENRL	Pyrexia/ Post #2 Vaccine Fever	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
>55/ C459100 1 1098 10981021	3^	MUSC	Arthralgia/ Right Ankle sore(pain)	1	10SEP2020	22/2	1	No	O	NA	R (11SEP2020)	N/N
>55/ C459100 1 1098 10981024	3^	RESP	Dyspnoea/ Shortness of Breath	2	01OCT2020	8/7	1	No	O	NA	R (07OCT2020)	N/N
		CARD	Angina unstable/ Unstable Angina Pectoris Moderate	2	04OCT2020	11/2	1	No	O	NA/TC	R (05OCT2020)	N/N
		CARD	Cardiac failure congestive/ Diastolic Congestive Heart Failure with acute exacerbation	2	07OCT2020	14/3	1	No	O	NA	R (09OCT2020)	N/N
		GENRL	Chest pain/ ChestPain	2	07OCT2020	14/3	1	No	O	NA/TC/TCN	R (09OCT2020)	Y/N
		INFEC	Pneumonia/ Community Acquired Pneumonia	2	07OCT2020	14/3	1	No	O	NA	R (09OCT2020)	Y/N
		INJ&P	Fall/ fall	2	07OCT2020	14/1	1	No	O	NA/TC	R (07OCT2020)	N/N
		NERV	Dizziness/ Dizziness	2	07OCT2020	14/1	1	No	O	NA/TC	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Chronic obstructive pulmonary disease/ COPD with acute exacerbation	2	07OCT2020	14/3	1	No	O	NA/TC	R (09OCT2020)	N/N
>55/ C459100 1 1098 10981133	3^	GENRL	Pain/ Bodyache	2	02OCT2020	4/1	1	Yes		NA/TC	R (02OCT2020)	N/N
			Pyrexia/ Fever	2	02OCT2020	4/1	1	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1098 10981158	3^	GENRL	Chills/ Chills	2	10OCT2020	6/1	1	Yes		NA/TC	R (10OCT2020)	N/N
			Pyrexia/ Fever	2	10OCT2020	6/1	1	Yes		NA/TC	R (10OCT2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	10OCT2020	6/1	1	Yes		NA/TC/TCN	R (10OCT2020)	N/N
>55/ C459100 1 1098 10981209	3^	INJ&P	Animal bite/ Catbite on Right index finger	1	13OCT2020	22/1	1	No	O	NA	R (13OCT2020)	N/N
>55/ C459100 1 1101 11011006	3^	GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
>55/ C459100 1 1101 11011008	3^	GENRL	Pyrexia/ fever	2	23SEP2020	2/6	1	Yes		NA	R (28SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11101 11011011	3^	GENRL	Injection site pain/ injection site pain	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N
>55/ C459100 11101 11011049	3^	GENRL	Fatigue/ fatigue	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ injection site pain	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/ injection site pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
>55/ C459100 11101 11011055	3^	GASTR	Gastroesophageal reflux disease/ worsening GERD	2	30OCT2020	26/C	2	No	O	NA	N	N/N
			Hiatus hernia/ hiatal hernia	2	30OCT2020	26/C	2	No	O	NA	N	N/N
>55/ C459100 11101 11011063	3^	GENRL	Chills/ chills	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
			Pain/ body aches	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
			Pyrexia/ low-grade fever	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11101 11011066	3^	GASTR	Abdominal discomfort/ upset stomach	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
			Diarrhoea/ diarrhea	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Injection site warmth/ warmth at injection site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Dizziness/ lightheadedness	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 11101 11011078	3^	GENRL	Injection site pain/ injection site pain	2	07OCT2020	1/3	2	Yes		NA	R (09OCT2020)	N/Y
>55/ C459100 11107 11071014	3^	RESP	Rhinorrhoea/ RHINORRHEA	1	05AUG2020	3/1	1	Yes		NA	R (05AUG2020)	N/N
>55/ C459100 11107 11071023	3^	INFEC	Eye infection/ LEFT EYE INFECTION	1	20AUG2020	18/7	1	No	O	NA/TC	R (26AUG2020)	N/N
>55/ C459100 11107 11071041	3^	NEOPL	Basal cell carcinoma/ BASAL CELL CARCINOMA RIGHT SHOULDER	1	11AUG2020	7/8	1	No	O	NA/TCN	R (18AUG2020)	N/N
>55/ C459100 11107 11071044	3^	HEPAT	Cholelithiasis/ CHOLELITHIASIS	2	11SEP2020	17/5	3	No	O	NA/TC/TCN	R (15SEP2020)	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11107 11071048	3^	GASTR	Toothache/ TOOTH PAIN	2	21SEP2020	27/2	1	No	O	NA/TC	R (22SEP2020)	N/N
>55/ C459100 11107 11071061	3^	INFEC	Conjunctivitis/ LEFT EYE CONJUNCTIVITIS	2	28AUG2020	2/7	1	No	O	NA/TC	R (03SEP2020)	N/N
		INFEC	Conjunctivitis/ LEFT EYE CONJUNCTIVITIS	2	24SEP2020	29/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 11107 11071090	3^	EYE	Cataract/ BILATERAL CATARACTS	2	08SEP2020	8/C	2	No	O	NA	N	N/N
>55/ C459100 11107 11071091	3^	INJ&P	Arthropod bite/ INSECT BITE RIGHT ARM	1	15AUG2020	5/4	1	No	O	NA/TC	R (18AUG2020)	N/N
>55/ C459100 11107 11071117	3^	GENRL	Chills/ CHILLS	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
			Fatigue/ FATIGUE	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
			Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
			Pyrexia/ FEVER	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1107 11071128	3^	MUSC	Myalgia/ MUSCLE PAIN (MYALGIAS)	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
		GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
>55/ C459100 1 1107 11071132	3^	NERV	Headache/ HEADACHE	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
		RESP	Oropharyngeal pain/ SORE THROAT	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
		GENRL	Chills/ CHILLS	2	08SEP2020	1/3	2	Yes		NA	R (10SEP2020)	N/N
			Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	2	08SEP2020	1/3	2	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1107 11071133	3^		Pyrexia/ FEVER	2	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN (MYALGIAS)	2	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ HEADACHE	2	10SEP2020	2/4	1	Yes		NA/TC	R (13SEP2020)	N/N
>55/ C459100 11107 11071148	3^	NERV	Dizziness postural/ POSTURAL CHANGE DIZZINESS	1	01SEP2020	13/3	1	No	O	NA	R (03SEP2020)	N/N
>55/ C459100 11107 11071149	3^	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
>55/ C459100 11107 11071150	3^	NERV	Dizziness postural/ POSTURAL CHANGE DIZZINESS	1	21AUG2020	2/15	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 11107 11071153	3^	GENRL	Chills/ CHILLS	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
		GENRL	Injection site pain/ RIGHT ARM INJECTION SITE PAIN	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Injection site pain/ RIGHT ARM PAIN (INJECTION ARM)	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 11107 11071166	3^	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	1	24AUG2020	1/5	1	Yes		NA/TC	R (28AUG2020)	N/N
>55/ C459100	3^	EYE	Vision blurred/ BLURRY VISION	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1107 11071167		NERV	Dizziness/ DIZZINESS	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
			Headache/ HEADACHE	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
>55/ C459100 1 1107 11071172	3^	GENRL	Injection site pain/ LEFT ARM INJECTION PAIN	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1107 11071183	3^	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
		RESP	Nasal congestion/ NASAL CONGESTION	1	01SEP2020	2/2	1	Yes		NA/TC	R (02SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	02SEP2020	3/2	1	Yes		NA	R (03SEP2020)	N/N
		MUSC	Myalgia/ MYALGIA (MUSCLE PAIN)	1	02SEP2020	3/2	1	Yes		NA	R (03SEP2020)	N/N
>55/ C459100 1 1107 11071197	3^	INJ&P	Animal bite/ CAT BITE RIGHT LOWER LEG	2	23OCT2020	31/7	1	No	O	NA/TC	R (29OCT2020)	N/N
>55/ C459100	3^	MUSC	Myalgia/ MYALGIA	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1107 11071214 >55/ C459100	3^	RENAL	Dysuria/ DYSURIA	1	21SEP2020	1/8	1	No	O	NA/TC	R (28SEP2020)	N/N
1 1107 11071216 >55/ C459100	3^	MUSC	Osteoarthritis/ LEFT HAND OSTEOARTHRITIS	1	29SEP2020	9/C	1	No	O	NA/TC	N	N/N
1 1107 11071217 >55/ C459100	3^	NERV	Headache/ HEADACHE	2	19AUG2020	2/2	3	Yes		NA/TC	R (20AUG2020)	N/N
1 1109 11091038 >55/ C459100	3^	MUSC	Back pain/ back pain	2	02SEP2020	15/C	2	No	O	NA/TC	RG	N/N
1 1109 11091049 >55/ C459100	3^	MUSC	Arthralgia/ LEFT MIDDLE FINGER PIP TENDERNESS	1	01AUG2020	1/28	1	No	O	NA	R (28AUG2020)	N/N
1 1109 11091084 >55/ C459100	3^	INV	Body temperature increased/ ELEVATED TEMPERATURE FOR 3 DAYS AFTER THE INJECTION	2	23AUG2020	1/4	1	Yes		NA/TC/TCN	R (26AUG2020)	N/N
1 1109 11091104 >55/ C459100	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	05AUG2020	3/3	1	Yes		NA	R (07AUG2020)	N/N
1 1109 11091107												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11109 11091111	3^	INV RESP	Body temperature increased/ ELEVATED TEMPERATURE Cough/ COUGH	1	05AUG2020	3/3	1	Yes		NA	R (07AUG2020)	N/N
>55/ C459100 11109 11091123	3^	INFEC MUSC	Diverticulitis/ Diverticulitis flair-up Arthritis/ Arthritis Flare	2	08NOV2020	78/6	4	No	O	NA/TC	R (13NOV2020)	Y/N
>55/ C459100 11109 11091123	3^	MUSC	Arthritis/ Arthritis Flare	2	17SEP2020	26/2	2	No	O	NA/TC	R (18SEP2020)	N/N
>55/ C459100 11109 11091135	3^	MUSC	Arthralgia/ Polyarthralgia	1	06AUG2020	4/1	1	No	O	NA	R (06AUG2020)	N/N
>55/ C459100 11109 11091149	3^	GENRL	Pyrexia/ FEVER FOR 1 DAY	1	07AUG2020	4/2	1	Yes		NA	R (08AUG2020)	N/N
>55/ C459100 11109 11091150	3^	MUSC	Myalgia/ QUADRICEP MYALGIA	1	06AUG2020	3/4	1	No	O	NA	R (09AUG2020)	N/N
>55/ C459100 11109 11091164	3^	VASC	Deep vein thrombosis/ Deep Vein Thrombosis	2	07SEP2020	15/C	4	No	O	NA/TC	RG	Y/N
>55/ C459100	3^	INJ&P	Fall/ FALL ON TENNIS COURT	2	18SEP2020	18/1	3	No	O	NA/TCN	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1109 11091206			Joint dislocation/ DISLOCATED LEFT SHOULDER	2	18SEP2020	18/1	3	No	O	NA/TCN	R (18SEP2020)	N/N
>55/ C459100 1 1109 11091210	3^	GASTR	Mouth ulceration/ ASYMPTOMATIC MOUTH ULCER	1	24AUG2020	12/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1109 11091276	3^	INFEC	Complicated appendicitis/ Acute appendicitis with necrosis	2	30SEP2020	22/3	4	No	O	NA/TC/TCN	R (02OCT2020)	Y/N
>55/ C459100 1 1109 11091281	3^	GENRL	Chills/ CHILLS	1	22AUG2020	2/1	2	Yes		NA	R (22AUG2020)	N/N
>55/ C459100 1 1109 11091293	3^	MUSC	Pyrexia/ FEVER Osteoarthritis/ Osteoarthritis right knee	1	22AUG2020	2/1	2	Yes		NA	R (22AUG2020)	N/N
>55/ C459100 1 1109 11091293	3^	MUSC	Osteoarthritis/ Osteoarthritis right knee	1	02SEP2020	12/C	3	No	O	NA/TC/TCN	RG	N/N
>55/ C459100 1 1109 11091318	3^	EAR	Vertigo/ Vertigo	1	24AUG2020	2/5	3	No	O	NA	R (28AUG2020)	N/N
>55/ C459100	3^	INJ&P	Facial bones fracture/ FACIAL BONE FRACTURE	1	12SEP2020	15/C	3	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1109 11091374			Fall/ Fall	1	12SEP2020	15/1	3	No	O	NA/TC	R (12SEP2020)	N/N
			Skin laceration/ FACIAL LACERATIONS	1	12SEP2020	15/C	3	No	O	NA/TC	RG	N/N
>55/ C459100 1 1109 11091387	3^	MUSC	Osteoarthritis/ Worsening osteoarthritis of the right knee	2	14OCT2020	23/2	4	No	O	NA/TC/TCN	R (15OCT2020)	Y/N
		VASC	Deep vein thrombosis/ Deep Vein Thrombosis (Right Leg)	2	20OCT2020	29/C	3	No	O	NA/TC	RG	N/N
>55/ C459100 1 1109 11091408	3^	GENRL	Injection site pain/ Injection Site Pain Left Arm	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1109 11091452	3^	MUSC	Myalgia/ Myalgia	2	10NOV2020	40/3	1	No	O	NA/TC	R (12NOV2020)	N/N
>55/ C459100 1 1109 11091503	3^	GASTR	Abdominal pain upper/ ABDOMINAL PAIN RUQ	1	SEP2020	1/	3	No	O	P	R (30SEP2020)	N/N
>55/ C459100 1 1109 11091537	3^	GENRL	Injection site pain/ Injection Site Pain Left Arm	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11109 11091558	3^	RESP	Dyspnoea/ Shortness of breath	2	06NOV2020	14/C	4	No	O	NA/TC	RG	Y/N
>55/ C459100 11110 11101017	3^	RENAL	Urinary retention/ URINARY RETENTION	2	08SEP2020	19/1	2	No	O	NA/TCN	R (08SEP2020)	N/N
>55/ C459100 11110 11101031	3^	METAB	Type 2 diabetes mellitus/ Diabetes Type 2	2	12NOV2020	80/C	4	No	O	NA/TC/TCN	RG	Y/N
>55/ C459100 11110 11101071	3^	INFEC	Tooth abscess/ molar abscess	1	15AUG2020	5/7	2	No	O	NA/TC	R (21AUG2020)	N/N
		NERV	Headache/ headache	1	16AUG2020	6/5	2	No	O	NA/TC/TCN	R (20AUG2020)	N/N
>55/ C459100 11110 11101074	3^	GASTR	Diarrhoea/ watery diarrhea	1	17AUG2020	6/1	1	No	O	NA	R (17AUG2020)	N/N
>55/ C459100 11110 11101104	3^	GASTR	Vomiting/ VOMIT	1	18AUG2020	1/1	1	No	O	NA	R (18AUG2020)	N/N
>55/ C459100 11110 11101119	3^	INV	Body temperature increased/ Elevated temperature	1	28AUG2020	10/1	1	No	O	NA/TC	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11110 11101133	3^	GASTR	Faeces soft/ WORSENING OF SOFT STOOL	1	09SEP2020	17/7	1	No	O	NA	R (15SEP2020)	N/N
>55/ C459100 11110 11101134	3^	GENRL	Chills/ chills	1	01SEP2020	9/2	1	No	O	NA	R (02SEP2020)	N/N
>55/ C459100 11110 11101136	3^	VASC	Hypertension/ hypertension	1	07SEP2020	14/C	1	No	O	NA/TC	N	N/N
>55/ C459100 11110 11101150	3^	MUSC	Pain in extremity/ pain to right fifth finger	2	14OCT2020	29/C	2	No	O	NA	RG	N/N
>55/ C459100 11110 11101152	3^	MUSC	Myalgia/ muscle pain	1	04SEP2020	8/1	1	No	O	NA	R (04SEP2020)	N/N
>55/ C459100 11110 11101166	3^	GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 11110 11101222	3^	PSYCH	Depression/ Depression	2	18OCT2020	21/C	1	No	O	NA/TC	N	N/N
>55/ C459100	3^	NERV	Diabetic neuropathy/ diabetic peripheral neuropathy	1	15SEP2020	7/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1110 11101225 >55/ C459100	3^	CARD	Ventricular extrasystoles/ Premature Ventricular Contraction	2	15OCT2020	11/C	1	No	O	NA/TC	N	N/N
1 1110 11101249 >55/ C459100	3^	GENRL	Fatigue/ fatigue	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
1 1110 11101272 >55/ C459100	3^	GENRL	Pyrexia/ fever	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
1 1110 11101288 >55/ C459100	3^	GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	2	Yes		NA/TC	R (14OCT2020)	N/N
1 1110 11101291 >55/ C459100	3^	GASTR	Diarrhoea/ loose stool	1	26SEP2020	5/1	1	No	O	NA	R (26SEP2020)	N/N
1 1110 11101303 >55/ C459100	3^	UNC	HYPERLIPIDEMIA@@/ Hyperlipidemia	2	30OCT2020	16/C	1	No	O	NA/TC	N	N/N
1 1110 11101306 >55/ C459100	3^	SKIN	Rash/ Skin Rash right forearm and left neck	1	02OCT2020	9/17	1	No	O	NA/TC	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		EYE	Ocular discomfort/ Eye Discomfort	2	16OCT2020	3/C	1	No	O	NA/TC	N	N/N
>55/ C459100 11110 11101310	3^	GENRL	Injection site pain/ soreness at site injection	2	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
		GENRL	Pain/ body aches	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
			Pyrexia/ Fever	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
		NERV	Headache/ headache	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
>55/ C459100 11111 11111011	3^	INV	Blood glucose increased/ Increase glucose level	2	22AUG2020	2/27	1	No	O	NA	R (17SEP2020)	N/N
		CARD	Palpitations/ Heart palpitations	2	26AUG2020	6/15	1	No	O	NA	R (09SEP2020)	N/N
>55/ C459100 11111 11111055	3^	MUSC	Neck pain/ neck pain	1	19AUG2020	14/27	2	No	O	NA	R (14SEP2020)	N/N
>55/ C459100 11111 11111084	3^	SKIN	Rash/ Rash (legs, arms, and stomach)	1	16AUG2020	7/46	2	No	O	NA/TC	R (30SEP2020)	N/N
		INFEC	Sinusitis/ SINUS INFECTION	1	20AUG2020	11/4	1	No	O	NA/TC	R (23AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Cough/ COUGH	1	20AUG2020	11/4	1	No	O	NA/TC	R (23AUG2020)	N/N
>55/ C459100 11111 11111091	3^	INJ&P	Joint injury/ LATERAL LEFT KNEE INJURY	1	30AUG2020	20/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 11111 11111095	3^	PSYCH	Mental disorder/ Undiagnosed Mental Disorder (not otherwise specified)	2	25SEP2020	25/C	2	No	O	NA	N	Y/N
>55/ C459100 11111 11111108	3^	PSYCH	Depression/ Exacerbation of depression	1	28AUG2020	15/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 11111 11111109	3^	INFEC	Pyelonephritis/ Pyelonephritis	2	28SEP2020	25/5	2	No	O	NA/TC	R (02OCT2020)	Y/N
>55/ C459100 11111 11111110	3^	MUSC	Pain in extremity/ Aches in the legs	1	14AUG2020	1/2	1	Yes		NA	R (15AUG2020)	N/N
		NERV	Headache/ Worsening headache	1	14AUG2020	1/2	1	Yes		NA	R (15AUG2020)	N/N
		NERV	Headache/ Worsening headache	1	20AUG2020	7/2	1	Yes		NA	R (21AUG2020)	N/N
		NERV	Headache/ Worsening headache	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11111 11111125	3^	GENRL	Chills/ Chills	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Pain/ Body ache	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 11111 11111140	3^	INFEC	Urinary tract infection/ Urinary tract infection	2	07OCT2020	29/6	2	No	O	NA/TC	R (12OCT2020)	N/N
>55/ C459100 11112 11121029	3^	SKIN	Rash/ Rash, scalp	2	09SEP2020	19/12	2	No	O	NA/TC	R (20SEP2020)	N/N
>55/ C459100 11112 11121034	3^	IMMUN	Food allergy/ Allergic reaction to chocolate	1	12AUG2020	10/6	1	No	O	NA/TC	R (17AUG2020)	N/N
>55/ C459100 11112 11121043	3^	INFEC	Tooth abscess/ Abscess tooth	2	17SEP2020	27/26	2	No	O	NA/TC	R (12OCT2020)	N/N
>55/ C459100 11112 11121118	3^	CARD	Tachycardia/ Tachycardia	1	12AUG2020	2/1	3	Yes		P/TC	R (12AUG2020)	N/N
		SKIN	Pruritus/ Generalized Pruritus	1	12AUG2020	2/1	3	Yes		NA/TC	R (12AUG2020)	N/N
>55/ C459100	3^	MUSC	Myalgia/ Muscle aches, back and left arm	2	22SEP2020	13/4	1	No	O	NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1112 11121131		MUSC	Intervertebral disc protrusion/ Herniated disc	2	26SEP2020	17/28	3	No	O	NA/TC/TCN	R (23OCT2020)	N/N
		VASC	Hypertension/ Worsening of Hypertension	2	05OCT2020	26/20	2	No	O	NA/TC	R (24OCT2020)	N/N
>55/ C459100 1 1112 11121153	3^	INFEC	Acute sinusitis/ Acute sinusitis	1	06SEP2020	18/4	2	No	O	NA/TC	R (09SEP2020)	N/N
>55/ C459100 1 1112 11121181	3^	INFEC	Otitis externa/ Otitis externa, bilateral	1	31AUG2020	5/5	2	No	O	NA/TC	R (04SEP2020)	N/N
>55/ C459100 1 1112 11121195	3^	GENRL	Injection site pain/ Injection site pain	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
>55/ C459100 1 1112 11121202	3^	GENRL	Fatigue/ Fatigue	1	03SEP2020	3/1	1	Yes		NA	R (03SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	1	03SEP2020	3/1	1	Yes		NA/TC	R (03SEP2020)	N/N
		INFEC	Sinusitis/ Rhinosinusitis	1	07SEP2020	7/6	1	No	O	NA/TC	R (12SEP2020)	N/N
		MUSC	Bursitis/ Trachanteric Bursitis	2	30SEP2020	9/17	2	No	O	NA/TC	R (16OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1112 11121205	3^	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		MUSC	Arthralgia/ Joint Pain, fingers	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N
			Myalgia/ Muscle aches	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1112 11121209	3^	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
>55/ C459100 1 1112 11121220	3^	GASTR	Diarrhoea/ Diarrhea	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	25SEP2020	2/4	1	Yes		NA	R (28SEP2020)	N/N
		MUSC	Arthralgia/ Joint pain, back, hips, knees, shoulders	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1112 11121223	3^	GENRL	Injection site erythema/ Redness at injection site	1	04SEP2020	2/5	1	Yes		NA	R (08SEP2020)	N/N
			Injection site pain/ Injection site pain	1	04SEP2020	2/5	1	Yes		NA	R (08SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1112 11121227	3^	INFEC	Paronychia/ Infected ingrown toenail, right big toe	1	14SEP2020	11/7	3	No	O	NA/TC	R (20SEP2020)	N/N
>55/ C459100 1 1112 11121230	3^	GENRL	Injection site pain/ Injection site pain, post vaccination	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
>55/ C459100 1 1112 11121235	3^	NERV	Headache/ Headache, post vaccination	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1112 11121236	3^	GENRL	Injection site pain/ Injection site pain, post vaccination	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		NERV	Headache/ Headache	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1112 11121241	3^	MUSC	Back pain/ Muscle Pain, back	1	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C459100 1 1112 11121247	3^	INJ&P	Meniscus injury/ Meniscus tear, left	1	16SEP2020	6/3	3	No	O	NA/TCN	R (18SEP2020)	N/N
>55/ C459100	3^	GENRL	Chills/ Chills	1	06OCT2020	1/2	2	Yes		P/TC	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1112 11121255			Pyrexia/ Fever	1	06OCT2020	1/2	2	Yes		P/TC	R (07OCT2020)	N/N
		MUSC	Myalgia/ Muscle Aches	1	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
		NERV	Headache/ Headaches	1	06OCT2020	1/2	3	Yes		P/TC	R (07OCT2020)	N/N
>55/ C459100 1 1112 11121276	3^	GENRL	Injection site pain/ Pain at injection	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1114 11141036	3^	INFEC	Herpes zoster/ Shingles Bilateral Back	2	25SEP2020	18/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1114 11141080	3^	INFEC	Staphylococcal infection/ MRSA infection Right Stump	1	12SEP2020	20/27	2	No	O	NA/TC	R (08OCT2020)	Y/N
		INJ&P	Skin injury/ skin avulsion, left finger	1	12SEP2020	20/1	2	No	O	NA	R (12SEP2020)	N/N
		MUSC	Pain in extremity/ bilateral hand pain	1	12SEP2020	20/2	1	No	O	NA	R (13SEP2020)	N/N
		RENAL	Acute kidney injury/ acute kidney injury	1	12SEP2020	20/C	2	No	O	NA/TC	N	N/N
		CARD	Atrial fibrillation/ Atrial fibrillation	1	14SEP2020	22/C	2	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Left ventricular hypertrophy/ Left Ventricular Hypertrophy	1	14SEP2020	22/C	1	No	O	NA	N	N/N
			Mitral valve incompetence/ mitral valve regurgitation	1	14SEP2020	22/C	1	No	O	NA	N	N/N
			Tricuspid valve incompetence/ Tricuspid regurgitation	1	14SEP2020	22/C	1	No	O	NA	N	N/N
		GENRL	Chest pain/ chest pain	1	14SEP2020	22/1	2	No	O	NA	R (14SEP2020)	N/N
		RESP	Pulmonary hypertension/ Pulmonary Hypertension	1	14SEP2020	22/C	1	No	O	NA	N	N/N
>55/ C459100 11114 11141101	3^	GASTR	Constipation/ Constipation	2	27SEP2020	12/5	1	No	O	NA/TC/TCN	R (01OCT2020)	N/N
		INFEC	Urinary tract infection/ urinary tract infection	2	13OCT2020	28/2	1	No	O	NA/TC/TCN	R (14OCT2020)	N/N
>55/ C459100 11116 11161005	3^	SKIN	Alopecia areata/ Intermittent Alopecia areata	2	01OCT2020	15/C	1	No	O	NA	N	N/N
>55/ C459100 11116 11161030	3^	UNC	RIB INJURY FROM FALL@@/ Rib Injury From Fall	2	29OCT2020	43/1	1	No	O	NA	R (29OCT2020)	N/N
>55/ C459100 11116 11161031	3^	GASTR	Large intestine polyp/ Colon Polyp	2	02OCT2020	16/1	1	No	O	NA/TC/TCN	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11116 11161045	3^	BLOOD	Thrombocytopenia/ Thrombocytopenia	2	27OCT2020	40/16	1	No	O	NA	R (11NOV2020)	Y/N
>55/ C459100 11116 11161075	3^	EAR	Tinnitus/ tinnitus	2	04OCT2020	13/C	1	No	O	NA	N	N/N
		SURG	Meniscus operation/ Repair torn meniscus	2	13OCT2020	22/1	1	No	O	NA/TC	R (13OCT2020)	N/N
>55/ C459100 11116 11161114	3^	GASTR	Vomiting/ Vomiting	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 11116 11161131	3^	BLOOD	Lymphadenopathy/ Left Axillary swollen lymph node	1	10SEP2020	7/5	2	Yes		NA	R (14SEP2020)	N/N
		GENRL	Injection site pain/ Muscle Pain @ injection site	1	10SEP2020	7/5	2	Yes		NA	R (14SEP2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Pain	1	10SEP2020	7/5	2	Yes		NA	R (14SEP2020)	N/N
			Myalgia/ Muscle Pain @ Chest Wall to Upper Back	1	10SEP2020	7/5	2	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11116 11161142	3^	METAB	Increased appetite/ increased appetite	1	09SEP2020	2/4	1	No	O	NA	R (12SEP2020)	N/N
		GENRL	Chills/ Chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		MUSC	Arthralgia/ Generalized Joint Pain	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
			Myalgia/ Muscle Pain	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 11116 11161161	3^	GASTR	Vomiting/ Vomiting	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Fatigue/ Fatigue/ Tiredness	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 11116 11161163	3^	INFEC	Furuncle/ Boil Left Hip Antecior	2	16OCT2020	18/8	1	No	O	NA	R (23OCT2020)	N/N
>55/ C459100 11116 11161184	3^	VASC	Hypertension/ Hypertension	2	27OCT2020	29/C	1	No	O	NA/TC/TCN	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11116 11161219	3^	INFEC	Influenza/ Influenza	2	29OCT2020	28/C	1	No	O	NA/TC/TCN	RG	N/N
>55/ C459100 11116 11161272	3^	RESP	Asthma/ Worsening Asthma	2	12OCT2020	1/C	1	No	O	NA/TC	N	N/N
>55/ C459100 11116 11161297	3^	INFEC	Bronchitis/ History of intermittent bronchitis	2	26OCT2020	11/5	1	No	O	NA/TC	R (30OCT2020)	N/N
>55/ C459100 11116 11161319	3^	GASTR	Diarrhoea/ Diarrhea	1	26SEP2020	2/2	1	No	O	NA/TC	R (27SEP2020)	N/N
>55/ C459100 11117 11171001	3^	NEOPL	Lipoma/ FATTY TUMOR, FOOT, LEFT, WORSENING	2	28SEP2020	20/1	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N
		INFEC	Sinusitis/ SINUSITIS	2	01OCT2020	23/14	1	No	O	NA/TC	R (14OCT2020)	N/N
		GASTR	Constipation/ CONSTIPATION	2	04OCT2020	26/7	2	No	O	NA/TC	R (10OCT2020)	N/N
			Gastrooesophageal reflux disease/ GERD EXACERBATION	2	04OCT2020	26/11	2	No	O	NA/TC	R (14OCT2020)	N/N
		VASC	Phlebolith/ PELVIC PHLEBOLITH	2	04OCT2020	26/32	1	No	O	NA	R (04NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11117 11171007	3^	HEPAT	Cholelithiasis/ GALL STONE	1	19AUG2020	3/C	2	No	O	NA/TCN	N	N/N
		MUSC	Spondylitis/ ARTHRITIC CHANGES, LUMBAR SPINE	1	19AUG2020	3/C	1	No	O	NA	N	N/N
		GASTR	Nausea/ NAUSEA	2	23SEP2020	16/2	1	No	CD	NA	R (24SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	23SEP2020	16/2	1	No	CD	NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ MYLAGIA	2	23SEP2020	16/2	1	No	CD	NA	R (24SEP2020)	N/N
		SURG	Sebaceous cyst excision/ RECURRENT SEBACEOUS CYST REMOVAL	2	01OCT2020	24/1	2	No	O	NA	R (01OCT2020)	N/N
>55/ C459100 11117 11171008	3^	METAB	Hyperkalaemia/ Hyperkalemia	1	03SEP2020	18/C	1	No	O	NA	RG	N/N
		MUSC	Tendonitis/ Right Hip Tendinitis	1	03SEP2020	18/8	2	No	O	NA/TC	R (10SEP2020)	N/N
		PSYCH	Anxiety/ Worsening Anxiety	1	03SEP2020	18/C	1	No	O	NA/TC	RG	N/N
		MUSC	Spinal osteoarthritis/ Osteoarthritis in Lower Back	1	04SEP2020	19/33	1	No	O	NA	R (06OCT2020)	N/N
>55/ C459100	3^	INJ&P	Fall/ FALL	2	17SEP2020	9/1	1	No	O	NA/TCN	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1117 11171013			Skin laceration/ LACERATION, FOREHEAD	2	17SEP2020	9/11	1	No	O	NA/TCN	R (27SEP2020)	N/N
>55/ C459100 1 1117 11171024	3^	GENRL	Temperature intolerance/ COLD INTOLERANCE	2	10SEP2020	2/C	1	No	O	NA	N	N/N
		INFEC	Paronychia/ PARONYCHIA, HANDS, BILATERAL	2	10SEP2020	2/C	1	No	O	NA	N	N/N
		MUSC	Muscle spasms/ CRAMP, LEG, UPPER, RIGHT	2	01OCT2020	23/6	1	No	O	NA	R (06OCT2020)	N/N
>55/ C459100 1 1117 11171025	3^	NERV	Aphasia/ APHASIA	2	30SEP2020	23/4	2	No	O	NA	R (03OCT2020)	N/N
			Paraesthesia/ PARWSTHESIA, BACK AND ARMS, BILATERAL	2	30SEP2020	23/4	2	No	O	NA	R (03OCT2020)	N/N
>55/ C459100 1 1117 11171027	3^	MUSC	Musculoskeletal stiffness/ NECK STIFFNESS	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1117 11171042	3^	Produ	Device connection issue/ LOOSE DENTAL FILLING	2	08OCT2020	25/1	1	No	O	NA/TCN	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ FATIGUE	2	12OCT2020	29/2	1	No	O	NA	R (13OCT2020)	N/N
>55/ C459100 11117 11171046	3^	INJ&P	Muscle strain/ Muscle Strain, Lumbar	1	13SEP2020	21/2	1	No	O	NA	R (14SEP2020)	N/N
>55/ C459100 11117 11171047	3^	CARD	Atrial fibrillation/ ATRIAL FIBRILLATION, EXACERBATION	2	15SEP2020	5/C	1	No	O	NA	RG	N/N
		RESP	Sleep apnoea syndrome/ SLEEP APNEA, OBSTRUCTIVE, MILD	2	22SEP2020	12/C	1	No	O	NA/TCN	RG	N/N
>55/ C459100 11117 11171059	3^	INFEC	Viral pharyngitis/ Pharyngitis, Viral	1	12SEP2020	19/5	1	No	O	NA/TCN	R (16SEP2020)	N/N
		GASTR	Gastroesophageal reflux disease/ GASTROESOPHAGIAL REFLUX	2	01OCT2020	14/10	1	No	O	NA/TC	R (10OCT2020)	N/N
>55/ C459100 11117 11171071	3^	INJ&P	Corneal abrasion/ CORNEA, SCRATCHED, RIGHT	1	11SEP2020	16/7	1	No	O	NA/TC	R (17SEP2020)	N/N
		UNC	SORE LYMPH NODES, NECK, RIGHT@@/ SORE LYMPH NODES, NECK, RIGHT	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11117 11171097	3 [^]	NERV	Periodic limb movement disorder/ INCREASED FREQUENCY PERIODIC LEG MOVEMENT	1	14SEP2020	11/18	1	No	O	NA/TC	R (01OCT2020)	N/N
		INJ&P	Ligament sprain/ SPRAIN, ANKLE, RIGHT	1	22SEP2020	19/16	1	No	O	NA/TC/TCN	R (07OCT2020)	N/N
		BLOOD	Iron deficiency anaemia/ IRON DEFICIENCY ANEMIA	2	07OCT2020	15/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C459100 11117 11171110	3 [^]	VASC	Hypertension/ HYPERTENSION, WORSENING	1	12SEP2020	2/21	1	No	O	NA/TC	R (02OCT2020)	N/N
>55/ C459100 11117 11171115	3 [^]	VASC	Hypertension/ HYPERTENSION, WORSENING	1	22SEP2020	9/10	1	No	O	NA/TC	R (01OCT2020)	N/N
		SKIN	Eczema/ ECZEMA, NECK, WORSENING	1	01OCT2020	18/8	1	No	O	NA/TC	R (08OCT2020)	N/N
>55/ C459100 11117 11171125	3 [^]	NERV	Headache/ HEADACHE	2	11NOV2020	29/C	1	No	O	NA	RG	N/N
>55/ C459100 11117 11171136	3 [^]	PSYCH	Anxiety/ WORSENING ANXIETY	1	22SEP2020	2/C	2	No	O	NA/TC	RG	N/N
>55/ C459100	3 [^]	INJ&P	Muscle strain/ THIGH MUSCLE, STRAIN, LEFT	1	11OCT2020	20/7	1	No	O	NA/TC	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1117 11171141 >55/ C459100	3^	MUSC	Back pain/ LOW BACK PAIN	1	10OCT2020	19/C	1	No	O	NA	RG	N/N
1 1117 11171142 >55/ C459100	3^	MUSC	Neck pain/ WORSENING CERVICALGIA	1	30SEP2020	8/C	2	No	O	NA	RG	N/N
1 1117 11171151		PSYCH	Insomnia/ WORSENING INSOMNIA	1	30SEP2020	8/32	2	No	O	NA/TC	R (31OCT2020)	N/N
		UNC	FUNGUS, TOES, RIGHT (SKIN OF TOES)@@/ FUNGUS, TOES, RIGHT (SKIN OF TOES)	2	OCT2020	1/C	1	No	O	NA/TC	RG	N/N
			FUNGUS, TOES, RIGHT (TOENAILS)@@/ FUNGUS, TOES, RIGHT (TOENAILS)	2	OCT2020	1/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1117 11171152	3^	GENRL	Vessel puncture site haematoma/ HEMATOMA, PHLEBOTOMY SITE*		23SEP2020	1/16	1	No	O	NA	R (08OCT2020)	N/N
>55/ C459100 1 1117 11171155	3^	SKIN	Dermatitis/ DERMATITIS, ARM, RIGHT, WORSENING	1	28SEP2020	6/C	1	Yes		NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11117 11171168	3^	GASTR	Swollen tongue/ SWOLLEN TONGUE	2	04NOV2020	21/C	2	No	O	NA	RG	N/N
>55/ C459100 11117 11171182	3^	MUSC	Arthralgia/ WORSENING KNEE PAIN, LEFT	1	06OCT2020	8/11	1	No	O	NA/TC	R (16OCT2020)	N/N
>55/ C459100 11118 11181020	3^	INFEC	Otitis externa/ Right ear otitis externa infection	2	24SEP2020	21/3	1	No	O	NA	R (26SEP2020)	N/N
>55/ C459100 11118 11181041	3^	INFEC	Ear infection/ right ear infection	2	06OCT2020	29/C	2	No	O	NA/TC	N	N/N
>55/ C459100 11118 11181044	3^	UNC	BILATERAL PULMONARY EMBOLISM@@/ bilateral pulmonary embolism	2	11NOV2020	65/C	3	No	O	NA/TC	RG	Y/N
>55/ C459100 11118 11181055	3^	GASTR	Constipation/ constipation	2	01NOV2020	53/1	1	No	O	NA/TC	R (01NOV2020)	N/N
>55/ C459100 11118 11181057	3^	INFEC	Diverticulitis/ Sigmoid diverticulitis	1	04SEP2020	18/15	3	No	O	NA/TC	R (18SEP2020)	Y/N
>55/ C459100	3^	MUSC	Musculoskeletal chest pain/ chest wall pain	2	14SEP2020	4/51	2	No	O	NA/TC	RS (03NOV2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1118 11181074		METAB	Gout/ GOUT RIGHT FOOT	2	06OCT2020	26/C	1	No	CD	NA/TC	N	N/N
>55/ C459100 1 1118 11181090	3^	INFEC	Herpes zoster/ Shingles	1	30AUG2020	4/C	1	No	O	NA	N	N/N
>55/ C459100 1 1120 11201008	3^	INV	Blood glucose increased/ Elevated blood sugar	1	02AUG2020	4/35	1	Yes		NA	R (05SEP2020)	N/N
		CARD	Atrial fibrillation/ atrial fibrillation	2	02SEP2020	15/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1120 11201025	3^	INJ&P	Tooth fracture/ Cracked Tooth	1	12AUG2020	10/30	2	No	CND	NA	R (10SEP2020)	N/N
		RESP	Oropharyngeal pain/ Sore Throat	1	14AUG2020	12/8	2	No	CND	NA/TC	R (21AUG2020)	N/N
>55/ C459100 1 1120 11201060	3^	INFEC	Otitis externa/ Otitis externa	1	20AUG2020	16/C	2	No	O	NA/TC/TCN	RG	N/N
>55/ C459100 1 1120 11201073	3^	RESP	Cough/ cough	1	08AUG2020	4/7	2	No	O	NA/TC	R (14AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11120 11201074	3^	INJ&P	Fall/ fall	2	18SEP2020	26/C	2	No	O	NA	N	N/N
			Skin abrasion/ GENERALIZED ABRASIONS	2	18SEP2020	26/C	2	No	O	NA/TC	N	N/N
		VASC	Haematoma/ HEMATOMA LEFT LATERAL THIGH	2	18SEP2020	26/C	2	No	O	NA/TC	N	N/N
>55/ C459100 11120 11201091	3^	INJ&P	Contusion/ bruising bilateral arms	1	24AUG2020	19/C	1	No	O	NA/TC	RG	N/N
			Fall/ Fall	1	24AUG2020	19/1	1	No	O	NA/TC	R (24AUG2020)	N/N
>55/ C459100 11120 11201124	3^	METAB	Hyperlipidaemia/ hyperlipidemia	2	08SEP2020	9/C	2	No	CD	NA/TC	N	N/N
>55/ C459100 11120 11201127	3^	GASTR	Diarrhoea/ Diarrhea	1	12AUG2020	2/3	3	Yes		P/TC/W	R (14AUG2020)	N/N
>55/ C459100 11120 11201137	3^	VASC	Hypertension/ worsening hypertension	1	02SEP2020	23/C	2	No	O	NA/TC	RG	N/N
>55/ C459100	3^	GASTR	Vomiting/ VOMITING	2	01OCT2020	30/1	1	No	O	NA	RS (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1120 11201141 >55/ C459100	3^	RENAL	Nephrolithiasis/ nephrolithiasis	2	07SEP2020	6/12	2	No	O	NA	R (18SEP2020)	N/N
1 1120 11201189 >55/ C459100	3^	INJ&P	Arthropod sting/ Sting by a yellow jacket left ring finger	1	04SEP2020	18/8	2	No	O	NA/TC	R (11SEP2020)	N/N
1 1120 11201227 >55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	2	12OCT2020	1/C	1	Yes		NA	N	N/Y
1 1120 11201287 >55/ C459100	3^	GENRL	Fatigue/ excessive fatigue	1	11SEP2020	4/3	1	Yes		NA	R (13SEP2020)	N/N
1 1122 11221013		GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ Fever 100.5 F	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		MUSC	Pain in extremity/ left arm soreness	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		NERV	Tremor/ trembling hands	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	11SEP2020	2/5	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1122 11221021			Pyrexia/ Feverish	1	11SEP2020	2/5	1	Yes		NA	R (15SEP2020)	N/N
		NERV	Tremor/ Shaky	1	11SEP2020	2/5	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	02OCT2020	2/5	1	Yes		NA	R (06OCT2020)	N/N
			Pyrexia/ feverish	2	02OCT2020	2/5	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1122 11221029	3^	GENRL	Injection site pain/ injection site soreness	2	02OCT2020	3/1	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1122 11221039	3^	GENRL	Injection site pain/ soreness at injection site	2	26OCT2020	1/C	1	Yes		NA	N	N/N
		GENRL	Chills/ chills	2	27OCT2020	2/C	1	Yes		NA	N	N/N
			Pyrexia/ fever	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		MUSC	Myalgia/ muscle aches	2	27OCT2020	2/C	1	Yes		NA	N	N/N
		NERV	Headache/ headache	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
>55/ C459100	3^	GENRL	Asthenia/ weakness	1	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1122 11221050			Fatigue/ fatigue	1	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
>55/ C459100 1 1123 11231025	3^	EYE	Conjunctival hyperaemia/ RIGHT EYE CONJUNCTIVE ERYTHEMA	2	24AUG2020	1/C	1	No	O	NA	N	N/N
>55/ C459100 1 1123 11231039	3^	INV	Blood pressure systolic increased/ Elevated systolic blood pressure*		05AUG2020	1/1	1	No	O	NA	R (05AUG2020)	N/N
>55/ C459100 1 1123 11231066	3^	GASTR	Vomiting/ Emesis	1	22AUG2020	12/1	1	No	O	NA	R (22AUG2020)	N/N
>55/ C459100 1 1123 11231070	3^	INJ&P	Radius fracture/ Left radius fracture	1	14AUG2020	4/C	1	No	O	NA/TC/TCN	RG	N/N
>55/ C459100 1 1123 11231089	3^	PSYCH	Mood swings/ Mood instability	1	14AUG2020	2/C	1	No	O	NA	N	N/N
>55/ C459100 1 1123 11231126	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	1/5	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ MUSCLE PAIN	2	09SEP2020	1/5	1	Yes		NA	R (13SEP2020)	N/N
>55/ C459100 11123 11231129	3^	INJ&P	Ear canal abrasion/ EXTERNAL AUDITORY CANAL ABRASION	1	09SEP2020	22/C	1	No	O	NA	N	N/N
>55/ C459100 11123 11231131	3^	GENRL	Injection site pain/ Injection site pain left arm	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N
>55/ C459100 11123 11231147	3^	GENRL	Injection site pain/ Injection site pain	2	14SEP2020	1/3	1	Yes		NA/TC	R (16SEP2020)	N/N
		MUSC	Myalgia/ Full body myalgia	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
>55/ C459100 11123 11231149	3^	NERV	Headache/ Headache	1	28AUG2020	5/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 11123 11231158	3^	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ Injection site pain	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ Full body myalgia	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11123 11231167	3^	NERV	Headache/ Headache	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Pyrexia/ Fever	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 11123 11231180	3^	NERV	Sciatica/ Worsening of sciatic nerve pain	1	29AUG2020	4/19	1	No	O	NA/TC	R (16SEP2020)	N/N
>55/ C459100 11123 11231198	3^	NERV	Headache/ Headache	1	27AUG2020	1/30	1	Yes		NA/TC	R (25SEP2020)	N/N
		GENRL	Oedema peripheral/ Peripheral edema	1	29AUG2020	3/C	1	No	O	NA	N	N/N
		GASTR	Abdominal pain/ Abdominal pain	1	07SEP2020	12/26	1	No	O	NA	R (02OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	12SEP2020	17/2	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Injection site erythema/ Redness at injection site	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	18SEP2020	1/15	1	Yes		NA	R (02OCT2020)	N/N
			Injection site swelling/ Swelling at injection site	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11123 11231219	3 [^]	GENRL	Chills/ CHILLS	2	19SEP2020	2/1	2	Yes		NA/TC	R (19SEP2020)	N/N
			Pyrexia/ FEVER	2	19SEP2020	2/1	2	Yes		NA/TC	R (19SEP2020)	N/N
		MUSC	Arthralgia/ JOINT PAIN	2	19SEP2020	2/1	2	Yes		NA/TC	R (19SEP2020)	N/N
			Myalgia/ FULL BODY MYALGIA	2	19SEP2020	2/7	2	Yes		NA/TC	R (25SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	09SEP2020	1/4	1	Yes		NA/TC	R (12SEP2020)	N/N
>55/ C459100 11123 11231259	3 [^]	NERV	Dysgeusia/ Metallic taste in mouth	1	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
		MUSC	Myalgia/ Left body myalgia	1	12SEP2020	4/5	1	Yes		NA/TC	R (16SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		GENRL	Chills/ Chills	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C459100 11123 11231316	3 [^]	RESP	Hiccups/ Hiccups	1	09OCT2020	16/3	1	No	O	NA/TC	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1123 11231331	3^	GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Malaise/ Malaise	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 1123 11231345	3^	INFEC	Bronchitis/ Bronchitis	1	24OCT2020	18/12	1	No	O	NA/TC	R (04NOV2020)	N/N
>55/ C459100 1 1124 11241033	3^	GASTR	Nausea/ Nausea	2	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		MUSC	Pain in extremity/ Painful fingers-Bilateral hands	2	02SEP2020	2/2	3	Yes		NA	R (03SEP2020)	N/N
		MUSC	Pain in extremity/ Painful toes-Bilateral feet	2	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N
		SKIN	Skin discolouration/ Discolored fingers-Bilateral hands	2	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N
		SKIN	Skin discolouration/ Discolored toes-Bilateral feet	2	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N
>55/ C459100 1 1124 11241037	3^	GENRL	Pyrexia/ Fever	2	03SEP2020	2/2	2	Yes		NA/TC	R (04SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	03SEP2020	2/2	2	Yes		NA/TC	R (04SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11124 11241046	3^	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/2	2	Yes		NA/TC	R (18AUG2020)	N/N
			Injection site erythema/ Injection site erythema	1	17AUG2020	1/2	2	Yes		NA	R (18AUG2020)	N/N
		MUSC	Myalgia/ Myalgia	1	17AUG2020	1/2	2	Yes		NA/TC	R (18AUG2020)	N/N
>55/ C459100 11124 11241048	3^	INFEC	Conjunctivitis bacterial/ Bacterial conjunctivitis	1	06SEP2020	21/6	2	No	O	NA/TC	R (11SEP2020)	N/N
>55/ C459100 11124 11241056	3^	GASTR	Gastroesophageal reflux disease/ Acid Reflux	2	06OCT2020	28/C	1	No	O	NA/TC	N	N/N
>55/ C459100 11124 11241063	3^	INJ&P	Limb fracture/ Fracture right third digit	2	05OCT2020	26/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 11124 11241074	3^	GENRL	Chills/ Chills	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N
		MUSC	Myalgia/ Body Aches/Myalgias	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N
		SKIN	Hyperhidrosis/ Sweating	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ Chills	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ Fever	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
		SKIN	Hyperhidrosis/ Sweats	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1124 11241082	3^	MUSC	Myalgia/ Muscle Aches (calves)	1	29AUG2020	6/3	1	No	O	NA	R (31AUG2020)	N/N
>55/ C459100 1 1124 11241085	3^	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/8	2	Yes		NA/TC	R (31AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/6	2	Yes		NA/TC	R (20SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	16SEP2020	2/1	2	Yes		NA/TC	R (16SEP2020)	N/N
>55/ C459100 1 1124 11241091	3^	GENRL	Injection site pruritus/ Injection site pruritus	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1124 11241107	3^	INJ&P	Animal bite/ Right Hand Dog Bite	2	04OCT2020	18/8	1	No	O	NA/TC	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11124 11241110	3^	GASTR	Diarrhoea/ Diarrhea/loose stool (1 episode)	1	02SEP2020	8/1	1	No	O	NA	R (02SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 11124 11241114	3^	IMMUN	Seasonal allergy/ Seasonal Allergies	1	30AUG2020	4/30	1	No	O	NA/TC	R (28SEP2020)	N/N
>55/ C459100 11124 11241116	3^	GENRL	Pyrexia/ Fever	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C459100 11124 11241121	3^	GENRL	Fatigue/ Fatigue	1	30AUG2020	4/1	2	Yes		NA	R (30AUG2020)	N/N
>55/ C459100 11124 11241124	3^	GENRL	Injection site pain/ Injection site pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 11124 11241128	3^	SKIN	Alopecia/ Hair loss	2	SEP2020	1/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11124 11241140	3^	INJ&P	Rib fracture/ Fractured Rib	1	22SEP2020	22/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 11124 11241144	3^	GENRL	Chills/ Chills	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Fatigue/ Fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 11124 11241145	3^	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/3	2	Yes		NA/TC	R (26SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C459100 11124 11241147	3^	MUSC	Back pain/ Worsening back pain	2	21OCT2020	30/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 11124 11241148	3^	GENRL	Injection site pain/ Injection site soreness	1	02SEP2020	1/5	1	Yes		NA	R (06SEP2020)	N/N
			Injection site warmth/ Injection site warmth	1	02SEP2020	1/5	1	Yes		NA	R (06SEP2020)	N/N
		GASTR	Nausea/ Nausea	1	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	1	03SEP2020	2/5	1	Yes		NA/TC	R (07SEP2020)	N/N
		GENRL	Injection site warmth/ Injection site warmth	2	23SEP2020	1/5	1	Yes		NA	R (27SEP2020)	N/N
		MUSC	Musculoskeletal stiffness/ Left arm stiffness	2	23SEP2020	1/5	1	Yes		NA	R (27SEP2020)	N/N
			Pain in extremity/ Left arm soreness	2	23SEP2020	1/5	1	Yes		NA	R (27SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	2/5	1	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C459100 11124 11241150	3^	INV	Body temperature increased/ Elevated Body Temperature	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 11124 11241151	3^	MUSC	Back pain/ Mild Lower back pain	2	07OCT2020	17/C	1	No	O	NA	RG	N/N
>55/ C459100 11124 11241154	3^	GENRL	Chills/ Chills	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
			Pyrexia/ Fever	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11124 11241157	3^	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
		GENRL	Injection site erythema/ Injection site redness	2	04OCT2020	11/2	2	Yes		NA/TC	R (05OCT2020)	N/N
>55/ C459100 11124 11241159	3^	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	1/6	2	Yes		NA	R (08SEP2020)	N/N
>55/ C459100 11124 11241160	3^	INFEC	Urinary tract infection/ Urinary tract infection	2	09OCT2020	16/9	1	No	O	NA/TC	R (17OCT2020)	N/N
>55/ C459100 11124 11241172	3^	GENRL	Chills/ Chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
			Pyrexia/ Fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ Worsening Headache	2	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	1	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11124 11241182		GENRL	Injection site pain/ Injection site pain	2	29SEP2020	1/3	1	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C459100 11124 11241191	3^	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	2/3	2	Yes		NA	R (12SEP2020)	N/N
		NERV	Headache/ Headache	1	11SEP2020	3/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Injection site erythema/ Injection Site Redness	1	12SEP2020	4/6	2	Yes		NA	R (17SEP2020)	N/N
		EAR	Tinnitus/ Tinnitus	2	02OCT2020	4/2	1	No	O	NA	R (03OCT2020)	N/N
		GENRL	Malaise/ Malaise	2	02OCT2020	4/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 11124 11241201	3^	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 11124 11241206	3^	NERV	Headache/ Worsening Headaches	2	30SEP2020	2/C	2	Yes		NA/TC	RG	N/N
>55/ C459100 11124 11241211	3^	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ Chills	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
			Fatigue/ Fatigue	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
		NERV	Headache/ Headache	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		MUSC	Bursitis/ Worsening bursitis of right hip	1	15SEP2020	6/C	2	No	O	NA/TC	RG	N/N
		GENRL	Chills/ Chills	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		MUSC	Myalgia/ Myalgias	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		NERV	Headache/ Headaches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1124 11241221	3^	GENRL	Injection site pain/ Injection site soreness	2	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N
>55/ C459100 1 1125 11251041	3^	INFEC	Cellulitis/ Cellulitis of Right Cheek	2	21SEP2020	18/13	1	No	O	NA/TC	R (03OCT2020)	N/N
>55/ C459100 1 1125 11251070	3^	GASTR	Gastric ulcer/ Gastric Ulcer	2	17SEP2020	7/C	2	No	O	NA/TC	RG	N/N
>55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1125 11251082		MUSC	Myalgia/ Myalgia	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
>55/ C459100 1 1125 11251107	3^	INJ&P	Muscle injury/ muscle sprain of lower back	1	12SEP2020	17/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1125 11251118	3^	MUSC	Bursitis/ Acute olecranon bursitis Left elbow	1	01SEP2020	6/C	2	No	O	NA	RG	N/N
>55/ C459100 1 1125 11251129	3^	ENDO	Hypogonadism/ hypogonadism	2	16OCT2020	24/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1125 11251147	3^	GENRL	Pain/ body aches	2	13OCT2020	19/1	1	No	O	NA	R (13OCT2020)	N/N
		INJ&P	Spinal compression fracture/ Compression fracture L4 vertebra	2	25OCT2020	31/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1125 11251161	3^	VASC	Hypertension/ Worsening of Hypertension	1	24SEP2020	22/15	2	No	O	NA/TC	R (08OCT2020)	N/N
>55/ C459100	3^	INFEC	Chronic sinusitis/ Exacerbation of chronic Sinusitis	1	21SEP2020	14/5	2	No	O	NA/TC	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1125 11251186 >55/ C459100	3^	IN FEC	Acute sinusitis/ acute sinus infection	1	14SEP2020	7/10	1	No	O	NA/TC	R (23SEP2020)	N/N
1 1125 11251190 >55/ C459100	3^	GEN RL	Chills/ Chills	1	28SEP2020	20/2	1	Yes		NA	R (29SEP2020)	N/N
1 1125 11251191			Pain/ bodyaches	1	28SEP2020	20/2	1	Yes		NA	R (29SEP2020)	N/N
			Pyrexia/ fever	1	28SEP2020	20/2	1	Yes		NA	R (29SEP2020)	N/N
		MUSC	Exostosis/ Osteophyte to lateral left foot	2	14OCT2020	17/C	1	No	O	NA	N	N/N
>55/ C459100 1 1125 11251210	3^	SKIN	Ecchymosis/ Ecchymosis	1	30SEP2020	20/8	1	No	O	NA	R (07OCT2020)	N/N
>55/ C459100 1 1125 11251211	3^	IN FEC	Bronchitis/ Bronchitis	1	18SEP2020	8/15	1	Yes		NA/TC	R (02OCT2020)	N/N
		NERV	Dizziness/ Dizziness	1	18SEP2020	8/15	2	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C459100	3^	MUSC	Pain in extremity/ Left arm pain	1	18AUG2020	2/7	1	Yes		NA	R (24AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1126 11261032 >55/ C459100 1 1126 11261036	3^	GENRL	Fatigue/ Fatigue	1	19AUG2020	2/7	1	Yes		NA	R (25AUG2020)	N/N
		MUSC	Axillary mass/ Subcutaneous mass, right axilla	1	26AUG2020	9/34	1	No	O	NA	R (28SEP2020)	N/N
		GENRL	Fatigue/ Fatigue, Intermittent	2	15SEP2020	8/10	2	No	O	NA	R (24SEP2020)	N/N
>55/ C459100 1 1126 11261038	3^	MUSC	Pain in extremity/ Left upper arm pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
		NERV	Headache/ Headache	1	19AUG2020	2/1	1	Yes		NA/TC	R (19AUG2020)	N/N
		GENRL	Injection site pain/ Pain, Injection site	2	08SEP2020	1/4	2	Yes		NA	R (11SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Headache	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
>55/ C459100 1 1126 11261051	3^	GENRL	Chills/ Chills	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Injection site pain/ Injection Site Pain	2	11SEP2020	2/5	2	Yes		NA/TC	R (15SEP2020)	N/N
			Pain/ Body Aches	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ Headache	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
>55/ C459100 1 1126 11261052	3^	NERV	Headache/ Headache	2	01OCT2020	21/2	1	No	O	NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1126 11261059	3^	INFEC	Pustule/ Skin pustule right hip	1	05SEP2020	16/6	1	No	O	NA/TC/TCN	R (10SEP2020)	N/N
		GENRL	Malaise/ Malaise	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1126 11261065	3^	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1126 11261066	3^	GENRL	Malaise/ Malaise	2	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100	3^	MUSC	Pain in extremity/ Left upper arm pain	2	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1126 11261067		GENRL	Chills/ Chills	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
			Fatigue/ Fatigue	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1126 11261070	3^	MUSC	Pain in extremity/ Upper left arm pain	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
		MUSC	Pain in extremity/ Upper left arm pain	2	15SEP2020	1/4	2	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1126 11261073	3^	MUSC	Pain in extremity/ Left upper arm pain	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
			Malaise/ Malaise	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
			Pyrexia/ Fever	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1126 11261077	3^	GENRL	Injection site pain/ Pain, injection site	1	27AUG2020	2/4	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Injection site erythema/ Injection site redness, left arm	2	16SEP2020	1/4	2	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1126 11261084	3^	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/11	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Malaise/ Malaise	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1126 11261087	3^	GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1126 11261088	3^	INV	Prostatic specific antigen increased/ Elevated Serum Prostate - Specific Antigen	1	28AUG2020	2/C	1	No	O	NA	N	N/N
>55/ C459100 1 1126 11261089	3^	MUSC	Pain in extremity/ Left upper arm pain	1	27AUG2020	1/3	1	Yes		NA/TC	R (29AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ Fatigue	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ Fever	2	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
			Pain in extremity/ Left upper arm pain	2	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N
>55/ C459100 11126 11261090	3^	GENRL	Injection site pain/ Injection site pain	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
>55/ C459100 11126 11261094	3^	MUSC	Pain in extremity/ Left Upper Arm Pain	2	16SEP2020	1/4	2	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 11126 11261098	3^	MUSC	Pain in extremity/ Left upper arm pain	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 11126 11261100	3^	GENRL	Injection site pain/ Inject site pain	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 11126 11261102	3^	GENRL	Mass/ Lump below left ear	1	31AUG2020	4/11	1	No	O	NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Malaise/ Malaise	2	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
			Pain/ Body aches	2	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
			Pyrexia/ Fever	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 11126 11261107	3^	MUSC	Arthralgia/ Left shoulder pain	2	22SEP2020	1/4	2	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 11126 11261110	3^	MUSC	Pain in extremity/ Left Upper Arm Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	27SEP2020	7/1	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 11126 11261119	3^	GENRL	Injection site pain/ Injection site pain	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Malaise/ Malaise	2	27SEP2020	4/2	2	Yes		NA	R (28SEP2020)	N/N
>55/ C459100 11126 11261120	3^	GENRL	Chills/ Chills	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1126 11261123	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ PAIN, INJECTION SITE	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site erythema/ INJECTION SITE REDNESS	2	25SEP2020	3/4	2	Yes		NA	R (28SEP2020)	N/N
>55/ C459100 1 1126 11261125	3^	EAR	Tinnitus/ Tinnitus Left Ear	1	02SEP2020	1/C	2	No	O	NA	N	N/N
>55/ C459100 1 1126 11261127	3^	GENRL	Fatigue/ Fatigue	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
			Malaise/ Malaise	1	03SEP2020	1/2	2	Yes		NA/TC	R (04SEP2020)	N/N
		MUSC	Pain in extremity/ Left upper arm pain	1	03SEP2020	1/6	2	Yes		NA/TC	R (08SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
			Injection site pain/ Pain, Injection site	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Muscle aches, left arm	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 11126 11261129	3^	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
>55/ C459100 11126 11261133	3^	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
			Fatigue/ Fatigue	2	25SEP2020	2/4	2	Yes		NA/TC	R (28SEP2020)	N/N
			Injection site pain/ Injection site pain	2	25SEP2020	2/4	1	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C459100 11126 11261139	3^	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	2/7	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Left upper arm injection pain	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	23SEP2020	1/2	2	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C459100 11126 11261140	3^	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1126 11261146	3^	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		GASTR	Nausea/ Nausea	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
			Malaise/ Malaise	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
			Pain/ Body aches	1	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
		NERV	Headache/ Headache	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		RENAL	Haematuria/ Hematuria	1	23SEP2020	16/4	2	No	O	NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1126 11261152	3^	GENRL	Chills/ Chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		INFEC	Hordeolum/ Stye right upper external eyelid	1	27SEP2020	19/3	1	No	O	NA/TCN	R (29SEP2020)	N/N
>55/ C459100 1 1126 11261153	3^	GENRL	Injection site pain/ Pain, injection site	1	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ Fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 11126 11261156	3^	GENRL	Injection site pain/ Injection site pain	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 11126 11261160	3^	NERV	Dizziness/ Light headedness	1	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/Y
		MUSC	Myalgia/ Muscle aches	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
			Pain in extremity/ Left upper arm pain	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 11126 11261162	3^	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
			Injection site pain/ Pain, Injection site	1	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
		RESP	Throat irritation/ Throat Irritation	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Chills/ Chills	2	01OCT2020	1/3	2	Yes		NA	R (03OCT2020)	N/N
			Injection site pain/ Injection site pain	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C459100 11126 11261163	3^	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		MUSC	Back pain/ Lower back pain	2	30SEP2020	1/3	2	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	1/3	2	Yes		NA	R (02OCT2020)	N/N
		GENRL	Pain/ Body aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 11126 11261169	3^	MUSC	Pain in extremity/ Left upper arm pain	1	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	02OCT2020	2/4	1	Yes		NA	R (05OCT2020)	N/N
			Injection site pruritus/ Injection site itchiness	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
			Pain/ Body aches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 11126 11261174	3^	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11126 11261175	3^	GENRL	Injection site pain/ Pain, injection site	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ Injection site pain	2	30SEP2020	1/5	2	Yes		NA	R (04OCT2020)	N/N
>55/ C459100 11126 11261176	3^	GENRL	Chills/ Body chills*		11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
			Injection site pain/ Pain, injection site*		11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Back pain/ Back pain	1	12SEP2020	2/1	3	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
			Fatigue/ Fatigue	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 11126 11261179	3^	NERV	Headache/ Headache	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		UNC	RENAL CALCULUS, WORSENING@@/ Renal Calculus, worsening	2	09OCT2020	3/1	1	No	O	NA	R (09OCT2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Pain, injection site	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1126 11261181 >55/ C459100 1 1127 11271006	2^	MUSC	Arthritis/ Arthritis in left thumb	2	03SEP2020	18/C	1	No	O	NA	N	N/N
		MUSC	Musculoskeletal pain/ Hip muscle pain bilateral exercise related	2	26SEP2020	41/C	1	No	O	NA	N	N/N
			Musculoskeletal pain/ knee muscle pain related to exercise	2	26SEP2020	41/C	1	No	O	NA	N	N/N
>55/ C459100 1 1127 11271007	2^	INFEC	Cystitis/ Bladder infection	1	07AUG2020	10/13	1	No	O	NA/TC	R (19AUG2020)	N/N
>55/ C459100 1 1127 11271019	3^	INJ&P	Fall/ fell off exercise bike	2	02SEP2020	16/1	1	No	O	NA	R (02SEP2020)	N/N
		MUSC	Arthralgia/ pain left hip	2	02SEP2020	16/C	1	No	O	NA	N	N/N
>55/ C459100 1 1127 11271023	3^	RESP	Asthma/ worsening of asthma	2	01OCT2020	45/C	1	No	O	NA/TC	N	N/N
		NEOPL	Invasive ductal breast carcinoma/ Malignant invasive ductal carcinoma left breast	2	05NOV2020	80/C	3	No	O	NA	N	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11127 11271031	3^	EAR	Ear pain/ earache	2	26SEP2020	39/4	1	No	O	NA	R (29SEP2020)	N/N
>55/ C459100 11127 11271034	3^	SKIN	Dermatitis contact/ Poison ivy contact dermatitis	1	13AUG2020	14/C	2	No	O	NA/TC	N	N/N
>55/ C459100 11127 11271046	3^	INFEC	Urinary tract infection/ Urinary tract infection	2	12SEP2020	22/C	1	No	O	NA/TC	N	N/N
>55/ C459100 11127 11271050	3^	INFEC	Gastroenteritis/ gastroenteritis	2	30SEP2020	38/C	1	No	O	NA/TC	N	N/N
>55/ C459100 11127 11271061	3^	INFEC	Sinusitis/ sinus infection	1	12AUG2020	8/10	1	No	O	NA/TC	R (21AUG2020)	N/N
>55/ C459100 11127 11271089	3^	INJ&P	Fall/ Fall	2	30AUG2020	1/1	1	No	O	NA	R (30AUG2020)	N/N
			Fibula fracture/ right fibula fracture	2	30AUG2020	1/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C459100 11128 11281014	3^	INJ&P	Fall/ Fall	2	28AUG2020	2/1	2	No	O	NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11128 11281053	3^	INJ&P	Skin laceration/ Facial Lacerations	2	28AUG2020	2/24	2	No	O	NA/TCN	R (20SEP2020)	Y/N
			Muscle strain/ Lower Back Strain	1	22AUG2020	18/15	2	No	O	NA/TC	R (05SEP2020)	N/N
>55/ C459100 11128 11281084	3^	GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	23/1	1	No	O	NA	R (24SEP2020)	N/N
>55/ C459100 11128 11281088	3^	GENRL	Pyrexia/ Subjective Fever	2	12SEP2020	10/1	1	No	O	NA	R (12SEP2020)	N/N
>55/ C459100 11128 11281150	3^	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	2	12SEP2020	10/1	1	No	O	NA	R (12SEP2020)	N/N
		GENRL	Pyrexia/ Subjective Fever	2	25SEP2020	23/1	1	No	O	NA	R (25SEP2020)	N/N
		INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	2	25SEP2020	23/1	1	No	O	NA	R (25SEP2020)	N/N
		PSYCH	Disorientation/ Disorientation	1	19AUG2020	1/2	2	Yes		NA	R (20AUG2020)	N/N
		GENRL	Chills/ Chill Episodes	1	20AUG2020	2/1	2	Yes		NA	R (20AUG2020)	N/N
		NERV	Somnolence/ Drowsyness	1	21AUG2020	3/2	2	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11128 11281179	3^	NERV	Lethargy/ Lethargic	2	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
			Pain/ body aches	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
		MUSC	Arthralgia/ sore left shoulder	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Pain/ Body aches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 11128 11281185	3^		Pyrexia/ Fever	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N
		INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	19SEP2020	4/5	2	No	O	NA/TC	R (23SEP2020)	N/N
>55/ C459100 11128 11281186	3^	GENRL	Injection site pain/ Injection Site Soreness	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 11128 11281191	3^	GENRL	Chills/ Chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100	3^	NEOPL	Basal cell carcinoma/ Skin, Left side Neck Basal Cell Carcinoma, Ulcerated	2	25SEP2020	12/C	2	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1128 11281207 >55/ C459100 1 1128 11281213	3^	GENRL	Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1128 11281215	3^	GASTR	Nausea/ Nausea	2	18SEP2020	1/3	2	Yes		NA/TC	R (20SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
>55/ C459100 1 1128 11281242	3^	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1128 11281264	3^	GENRL	Pain/ Body Aches	1	02SEP2020	1/3	1	Yes		NA/TC	R (04SEP2020)	N/N
		GENRL	Pain/ Body Aches	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1128 11281278	3^	NEOPL	Squamous cell carcinoma/ SQUAMOUS CELL CARCINOMA, RIGHT LATERAL TEMPLE	2	01OCT2020	9/5	2	No	O	NA	R (05OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11128 11281293	3^	GENRL	Injection site pain/ injection site soreness	2	30SEP2020	2/5	1	Yes		NA	R (04OCT2020)	N/N
>55/ C459100 11128 11281298	3^	GENRL	Injection site pain/ Soreness at injection site	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Pyrexia/ Subjective Fever	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 11128 11281308	3^	GENRL	Fatigue/ Fatigue (Vaccine Reaction)	1	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ Injection site Left Arm Soreness (Vaccine Reaction)	1	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ Fatigue (vaccine reaction)	2	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N
		GENRL	Injection site pain/ injection site Left Arm Soreness (Vaccine Reaction)	2	14OCT2020	2/3	2	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 11128 11281314	3^	GENRL	Injection site pain/ Left Arm Injection Site Soreness	1	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Left Arm Injection Site Soreness	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11128 11281320	3^	EAR	Vertigo/ Vertigo	2	08OCT2020	10/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 11128 11281321	3^	GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
			Pain/ Body Aches	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
			Pyrexia/ Fever	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
		NERV	Headache/ Headache	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
>55/ C459100 11128 11281346	3^	INFEC	Furuncle/ BOIL, TOP OF HEAD	2	05OCT2020	3/6	2	No	O	NA/TC	R (10OCT2020)	N/N
>55/ C459100 11128 11281351	3^	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	29OCT2020	27/10	2	No	O	NA/TC	R (07NOV2020)	N/N
>55/ C459100 11128 11281354	3^	GENRL	Injection site pain/ Injection Site Soreness	2	08OCT2020	2/5	1	Yes		NA/TC	R (12OCT2020)	N/N
			Injection site pain/ Left Side of Neck to Injection Site Soreness	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1128 11281356	3^	NERV	Pain/ Body Aches	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
			Pyrexia/ Subjective Fever	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
			Headache/ Worsening of Headache	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
		GENRL	Chills/ Chills	1	16SEP2020	3/2	1	Yes		NA	R (17SEP2020)	N/N
					Pain/ Body aches	1	16SEP2020	3/2	1	Yes		NA
>55/ C459100 1 1128 11281380	3^	GENRL	Pyrexia/ Fever	1	16SEP2020	3/2	1	Yes		NA	R (17SEP2020)	N/N
			Chills/ Chills	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		SKIN	Rash/ Bilateral Armpit Rash	2	18OCT2020	11/6	1	No	O	NA/TC	R (23OCT2020)	N/N
>55/ C459100 1 1128 11281383	3^	GENRL	Fatigue/ FATIGUE	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ LEFT ARM injection site PAIN	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pain/ BODY ACHES	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 11129 11291008	2^	SKIN	Dermatitis/ Back Dermatitis	1	12AUG2020	15/31	2	No	O	NA/TC	R (11SEP2020)	N/N
>55/ C459100 11129 11291028	3^	METAB	Type 2 diabetes mellitus/ Worsened type 2 diabetes	2	08SEP2020	21/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 11129 11291035	3^	GENRL	Swelling/ bilateral transient neck tissue swelling	1	03AUG2020	1/2	1	Yes		NA	R (04AUG2020)	N/N
>55/ C459100 11129 11291044	3^	INFEC	Cellulitis/ left arm cellulitis	2	17SEP2020	24/32	2	No	O	NA	R (18OCT2020)	N/N
>55/ C459100 11129 11291057	3^	INJ&P	Limb injury/ right great toe avulsion injury	1	14AUG2020	8/48	1	No	O	NA/TC	R (30SEP2020)	N/N
>55/ C459100 11129 11291059	3^	BLOOD	Lymphadenopathy/ Left supraclavicular adenopathy	2	31AUG2020	4/C	1	Yes		NA/TCN	RG	N/N
>55/ C459100 11129 11291074	3^	EAR	Vertigo/ Worsened Vertigo	1	21AUG2020	12/4	3	No	O	NA	R (24AUG2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1129 11291075	3^	EYE	Diplopia/ double vision	1	21AUG2020	12/2	3	No	O	NA	R (22AUG2020)	Y/N
		INJ&P	Skin abrasion/ Abrasion left middle toe	2	18SEP2020	19/46	2	No	O	NA/TC	R (02NOV2020)	N/N
		INFEC	Herpes virus infection/ worsened recurrent herpetic lesion, gluteal area	2	21OCT2020	52/13	1	No	O	NA	R (02NOV2020)	N/N
>55/ C459100 1 1129 11291090	3^	ENDO	Hypothyroidism/ Hypothyroidism-Subject was prescribed Levothyroxine 50 po qd on 18sep2020	2	18SEP2020	19/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1129 11291108	3^	GASTR	Abdominal distension/ intermittent bloating	1	18AUG2020	2/14	1	No	O	NA	R (31AUG2020)	N/N
>55/ C459100 1 1129 11291113	3^	MUSC	Flatulence/ intermittent flatulence	1	18AUG2020	2/14	1	No	O	NA	R (31AUG2020)	N/N
			Back pain/ worsening back pain	2	26SEP2020	19/38	2	No	O	NA/TC	R (02NOV2020)	N/N
>55/ C459100 1 1129 11291114	3^	CARD	Mitral valve prolapse/ Mitral Valve prolapse	2	06OCT2020	29/C	1	No	O	NA	N	N/N
>55/ C459100	3^	RENAL	Urinary retention/ Urinary retention with emergency catheter	1	04SEP2020	18/36	2	No	O	NA/TCN	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1129 11291123												
>55/ C459100 1 1129 11291132	3^	GASTR	Diarrhoea/ diarrhea	2	24SEP2020	11/1	1	No	O	NA	R (24SEP2020)	N/N
		NERV	Headache/ headache	2	05OCT2020	22/4	1	No	O	NA	R (08OCT2020)	N/N
>55/ C459100 1 1129 11291138	3^	INFEC	Osteomyelitis/ osteomyelitis distal phalanx right 3rd toe	1	31AUG2020	7/27	3	No	O	NA/TC	R (26SEP2020)	Y/N
		EYE	Retinal detachment/ detached left retina	2	26OCT2020	42/3	2	No	O	NA/TC/TCN	R (28OCT2020)	N/N
>55/ C459100 1 1129 11291139	3^	MUSC	Myalgia/ Left Deltoid Tenderness	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		SKIN	Erythema/ Left deltoid erythema	1	25AUG2020	1/2	2	Yes		NA	R (26AUG2020)	N/N
		GENRL	Fatigue/ fatigue	1	15SEP2020	22/2	2	Yes		NA	R (16SEP2020)	N/N
		MUSC	Arthralgia/ Joint Pain	1	15SEP2020	22/2	2	Yes		NA/TC	R (16SEP2020)	N/N
			Myalgia/ Muscle pain	1	15SEP2020	22/2	2	Yes		NA/TC	R (16SEP2020)	N/N
		NERV	Headache/ Headache	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11129 11291173	3^	INFEC	Urinary tract infection/ Urinary tract infection	2	31OCT2020	47/9	2	No	O	NA/TC	R (08NOV2020)	N/N
		GENRL	Asthenia/ weakness	2	04NOV2020	31/1	2	No	O	NA/TCN	R (04NOV2020)	N/N
>55/ C459100 11129 11291175	3^	SKIN	Hyperhidrosis/ diaphoresis	2	04NOV2020	31/1	2	No	O	NA/TCN	R (04NOV2020)	N/N
		INFEC	Urinary tract infection/ urinary tract infection	2	23OCT2020	19/13	2	No	O	NA/TC	R (04NOV2020)	N/N
>55/ C459100 11129 11291183	3^	MUSC	Arthralgia/ left shoulder soreness	1	18SEP2020	4/2	2	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C459100 11129 11291188	3^	GENRL	Injection site pain/ left arm injection site muscle pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 11129 11291191	3^	INJ&P	Arthropod bite/ let lower leg insect bite	1	09OCT2020	19/3	1	No	O	NA/TC	R (11OCT2020)	N/N
		SKIN	Urticaria/ allergic urticaria-bilateral hands	1	11OCT2020	21/C	1	No	O	NA/TC	RG	N/N
			Urticaria/ allergic urticaria-bilateral legs	1	11OCT2020	21/C	1	No	O	NA/TC/TCN	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11129 11291206	3^	NERV	Dizziness/ Intermittent dizziness	1	02OCT2020	5/C	1	No	O	NA	N	N/N
>55/ C459100 11129 11291207	3^	GENRL	Chills/ chills	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
			Pyrexia/ fever	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
>55/ C459100 11130 11301009	3^	RENAL	Dysuria/ Dysuria	1	01SEP2020	7/50	1	No	O	NA	R (20OCT2020)	N/N
>55/ C459100 11130 11301039	3^	GASTR	Colitis microscopic/ microscopic colitis	1	11SEP2020	9/61	2	No	O	NA/TC	R (10NOV2020)	N/N
		INV	Blood pressure increased/ Worsened Acute Blood Pressure Elevation	2	04OCT2020	5/1	2	No	O	NA	R (04OCT2020)	N/N
		MUSC	Back pain/ Acute Back Pain	2	04OCT2020	5/1	2	No	O	NA	R (04OCT2020)	N/N
>55/ C459100 11131 11311008	3^	GASTR	Dyspepsia/ nausea/ dyspepsia	1	14AUG2020	2/33	1	Yes		NA/TC	R (15SEP2020)	N/N
>55/ C459100	3^	GENRL	Chills/ chills	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1131 11311023		NERV	Headache/ headache	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
		RESP	Epistaxis/ epistaxis	2	10OCT2020	33/1	1	No	O	NA/TCN	R (10OCT2020)	N/N
>55/ C459100 1 1131 11311034	3^	GENRL	Chills/ chills	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	11SEP2020	2/5	1	Yes		NA/TC	R (15SEP2020)	N/N
			Pyrexia/ fever	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
		MUSC	Back pain/ low back pain	2	11SEP2020	2/8	1	Yes		NA/TC	R (18SEP2020)	N/N
			Musculoskeletal discomfort/ hip discomfort	2	11SEP2020	2/8	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1131 11311040	3^	NERV	Headache/ headache	2	09SEP2020	2/1	2	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 1 1131 11311043	3^	GASTR	Toothache/ dental pain	2	10OCT2020	30/C	2	No	O	NA/TCN	N	N/N
		GASTR	Gastritis/ exacerbation of gastritis	2	27OCT2020	47/8	1	No	O	NA/TC	R (03NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11131 11311044	3^	GASTR	Abdominal distension/ abdominal bloating	1	26AUG2020	8/6	1	No	O	NA/TC	R (31AUG2020)	N/N
>55/ C459100 11131 11311056	3^	GASTR	Nausea/ nausea	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 11131 11311057	3^	MUSC	Dupuytren's contracture/ Dupuytren's Contracture, left fifth digit	2	22SEP2020	12/C	1	No	O	NA	N	N/N
			Dupuytren's contracture/ Dupuytren's Contracture, right fifth digit	2	22SEP2020	12/10	2	No	O	NA/TCN	R (01OCT2020)	N/N
		INFEC	Herpes zoster/ shingles	2	30SEP2020	20/C	2	No	O	NA/TC	RG	N/N
		INFEC	Postoperative wound infection/ Postoperative wound infection at right hand, 5th digi	2	07OCT2020	27/18	2	No	O	NA/TC	R (24OCT2020)	N/N
>55/ C459100 11131 11311059	3^	MUSC	Spinal stenosis/ Spinal Stenosis diagnosed	1	27AUG2020	8/C	2	No	O	NA/TCN	N	N/N
>55/ C459100 11131 11311088	3^	GENRL	Injection site pain/ pain at injection site	2	15SEP2020	1/4	1	Yes		NA/TC	R (18SEP2020)	N/N
		MUSC	Arthralgia/ increasing joint pain	2	SEP2020	1/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11131 11311095	3^	INJ&P	Muscle strain/ muscle strain	2	23SEP2020	9/9	2	No	O	NA	R (01OCT2020)	N/N
		MUSC	Pain in extremity/ left forearm pain	2	23SEP2020	9/C	2	No	O	NA/TC	N	N/N
		BLOOD	Lymphadenopathy/ swollen axillary lymph nodes	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Malaise/ malaise	2	30SEP2020	2/2	1	Yes		NA	RS (01OCT2020)	N/N
		NERV	Headache/ headache	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 11131 11311110	3^	MUSC	Myalgia/ generalized myalgia	2	02OCT2020	4/1	2	Yes		NA	R (02OCT2020)	N/N
		MUSC	Back pain/ low back pain	1	15SEP2020	16/10	1	No	CD	NA/TC	R (24SEP2020)	N/N
>55/ C459100 11131 11311114	3^	GENRL	Injection site pain/ injection site arm pain	2	24SEP2020	1/5	1	Yes		NA	R (28SEP2020)	N/N
>55/ C459100 11131 11311125	3^	SKIN	Rash/ rash on both arms and legs	1	13SEP2020	12/19	1	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1131 11311130		GENRL	Fatigue/ fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 1 1131 11311137	3^	GENRL	Pain/ Body aches	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1131 11311140	3^	MUSC	Myalgia/ muscle pain	2	24SEP2020	1/5	2	Yes		NA/TC	R (28SEP2020)	N/N
		NERV	Headache/ headache	2	24SEP2020	1/5	2	Yes		NA/TC	RG (28SEP2020)	N/N
		MUSC	Arthralgia/ generalized joint pain	2	25SEP2020	2/34	2	Yes		NA/TC	R (28OCT2020)	N/N
>55/ C459100 1 1131 11311145	3^	GENRL	Asthenia/ generalized weakness, intermittent	1	SEP2020	1/C	2	No	CD	NA	N	N/N
		INJ&P	Fall/ Frequent falls	1	SEP2020	1/C	2	No	CD	NA	N	N/N
			Skin abrasion/ abrasion of right forearm	1	SEP2020	1/C	1	No	CD	NA	N	N/N
		NERV	Paraesthesia/ tingling of bilateral limbs, intermittent	1	SEP2020	1/C	1	No	CD	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11131 11311149	3^	CARD	Atrial fibrillation/ Atrial fibrillation with rapid ventricular response	1	08OCT2020	31/6	2	No	O	NA/TC	R (13OCT2020)	N/N
		METAB	Hypovolaemia/ hypovolemia	1	08OCT2020	31/6	2	No	O	NA/TC	R (13OCT2020)	N/N
		NERV	Syncope/ Syncope	1	08OCT2020	31/6	3	No	O	NA/TC	R (13OCT2020)	Y/N
		METAB	Hypovolaemia/ hypovolemia	1	18OCT2020	41/8	2	No	O	NA	R (25OCT2020)	N/N
		VASC	Orthostatic hypotension/ Hypotension, orthostatic	1	18OCT2020	41/8	3	No	O	NA/TC	R (25OCT2020)	Y/N
		NEOPL	Basal cell carcinoma/ basal cell carcinoma	1	09SEP2020	2/1	1	No	O	NA/TCN	R (09SEP2020)	N/N
		GENRL	Chills/ chills	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		GENRL	Fatigue/ fatigue	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N
		GENRL	Pyrexia/ low grade temperature injection	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		NERV	Headache/ headache	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 11131 11311150	3^	PSYCH	Irritability/ irritable mood	2	04OCT2020	7/23	2	Yes		NA	R (26OCT2020)	N/N
>55/ C459100	3^	GENRL	Non-cardiac chest pain/ non-cardiac chest pain	2	26OCT2020	29/1	3	No	O	NA/TC	R (26OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1131 11311154 >55/ C459100	3^	MUSC	Arthralgia/ joint pain in hands	1	17SEP2020	9/C	2	Yes		NA	RG	N/N
1 1131 11311156 >55/ C459100	3^	EYE	Blepharitis/ left eye blepharitis	1	28SEP2020	19/8	1	No	O	NA/TC	R (05OCT2020)	N/N
1 1131 11311163 >55/ C459100	3^	MUSC	Myalgia/ muscle aches	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
1 1131 11311168 >55/ C459100	3^	GENRL	Axillary pain/ left axillary pain	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
1 1131 11311180			Fatigue/ fatigue	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
			Injection site pain/ injection site pain, left deltoid	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
		SKIN	Rash/ rash on trunk	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C459100 1 1131 11311185	3^	MUSC	Myalgia/ left lower abdomen muscle pain	1	06OCT2020	20/5	1	No	O	NA/TC	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11131 11311188	3^	GENRL	Injection site pain/ injection site pain	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		INV	Body temperature increased/ temperature elevation	2	08OCT2020	1/2	1	Yes		NA/TCN	R (09OCT2020)	N/N
>55/ C459100 11131 11311195	3^	GENRL	Fatigue/ fatigue	2	10OCT2020	2/2	2	Yes		NA	R (11OCT2020)	N/N
			Injection site pain/ injection site pain	2	10OCT2020	2/2	2	Yes		NA	R (11OCT2020)	N/N
>55/ C459100 11131 11311206	3^	GENRL	Injection site pain/ arm soreness at injection site	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N
		MUSC	Myalgia/ generalized muscle pain	2	16OCT2020	2/3	2	Yes		NA/TC	R (18OCT2020)	N/N
>55/ C459100 11131 11311211	3^	GENRL	Injection site pain/ pain at injection site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ generalized myalgia	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N
		INV	Body temperature increased/ elevated temperature	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
>55/ C459100	3^	MUSC	Myalgia/ right upper posterior thigh muscle pain	1	05OCT2020	12/C	1	No	O	NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1131 11311213		INJ&P	Contusion/ bruising left knee	2	01NOV2020	20/C	1	No	O	NA/TC	RG	N/N
			Contusion/ right arm with bruises	2	01NOV2020	20/C	2	No	O	NA	RG	N/N
			Fall/ fall	2	01NOV2020	20/1	2	No	O	NA	RS (01NOV2020)	N/N
			Skin abrasion/ abrasion right arm	2	01NOV2020	20/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1131 11311214	3^	GENRL	Chills/ chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
			Injection site pain/ injection site/arm pain	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ muscle pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 1131 11311216	3^	EAR	Vertigo/ recurrence of vertigo	1	04OCT2020	11/3	1	No	O	NA	R (06OCT2020)	N/N
		EAR	Vertigo/ recurrence of vertigo	2	12NOV2020	29/1	1	No	O	NA	R (12NOV2020)	N/N
>55/ C459100 1 1131 11311222	3^	CONG	Heart disease congenital/ congenital heart anomaly	2	02NOV2020	18/C	4	No	O	NA/TC	N	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11131 11311223	3^	MUSC	Myalgia/ myalgia	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
		NERV	Lethargy/ lethargy	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 11131 11311225	3^	EYE	Vitreous floaters/ Floater in left eye	1	11OCT2020	17/C	1	No	O	NA	N	N/N
>55/ C459100 11131 11311227	3^	GENRL	Swelling face/ left side facial swelling	1	18OCT2020	21/C	2	No	O	NA/TC	N	N/N
		INJ&P	Arthropod sting/ bee sting	1	18OCT2020	21/1	2	No	O	NA/TC	R (18OCT2020)	N/N
		SKIN	Urticaria/ hives, upper torso	1	18OCT2020	21/1	2	No	O	NA/TC	R (18OCT2020)	N/N
>55/ C459100 11131 11311235	3^	GENRL	Injection site pain/ right arm pain at injection site	1	09OCT2020	1/4	1	Yes		NA	R (12OCT2020)	N/N
>55/ C459100 11133 11331006	3^	PSYCH	Bipolar disorder/ Worsening Bipolar Disorder	2	24AUG2020	4/12	3	No	O	NA/TC/TCN	R (04SEP2020)	Y/N
		INFEC	Urinary tract infection/ Urinary tract infection	2	05OCT2020	46/10	3	No	O	NA	R (14OCT2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1133 11331031	3^	NERV	Syncope/ Syncope	2	05OCT2020	46/1	3	No	O	NA/TC	R (05OCT2020)	N/N
		GENRL	Pain/ body aches	2	21AUG2020	1/8	1	Yes		NA/TCN	R (28AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	28AUG2020	8/4	1	Yes		NA	R (31AUG2020)	N/N
			Injection site erythema/ Redness at the injection site	2	28AUG2020	8/4	2	Yes		NA/TC	R (31AUG2020)	N/N
			Injection site pain/ Injection site pain	2	28AUG2020	8/4	2	Yes		NA/TC	R (31AUG2020)	N/N
			Injection site swelling/ Swelling at the injection site	2	28AUG2020	8/4	2	Yes		NA/TC	R (31AUG2020)	N/N
>55/ C459100 1 1133 11331075	3^	GENRL	Pain/ Body Aches	2	28AUG2020	8/4	1	Yes		NA	R (31AUG2020)	N/N
			Injection site swelling/ INJECTION SITE SWELLING	2	04SEP2020	8/4	1	Yes		NA	R (07SEP2020)	N/N
			Pain/ right upper deltoid pain	2	04SEP2020	8/4	1	Yes		NA	R (07SEP2020)	N/N
>55/ C459100 1 1133 11331085	3^	SKIN	Erythema/ right upper deltoid redness	2	04SEP2020	8/4	1	Yes		NA	R (07SEP2020)	N/N
		EAR	Vertigo/ VERTIGO	1	28AUG2020	22/1	2	No	O	NA/TC	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1133 11331169	3^	RESP	Cough/ DRY COUGH	2	12SEP2020	9/8	2	No	O	NA/TC	R (19SEP2020)	N/N
			Upper-airway cough syndrome/ POST NASAL DRIP	2	12SEP2020	9/8	2	No	O	NA/TC	R (19SEP2020)	N/N
>55/ C459100 1 1133 11331176	3^	NERV	Tension headache/ tension headache	2	29SEP2020	26/2	2	No	O	NA/TC	R (30SEP2020)	N/N
>55/ C459100 1 1133 11331199	3^	GENRL	Chills/ Chills	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
>55/ C459100 1 1133 11331220	3^	GENRL	Pyrexia/ fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Arthralgia/ joint pain	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1133 11331227	3^	INJ&P	Fall/ Fall	1	09SEP2020	17/1	2	No	O	NA/TC	R (09SEP2020)	N/N
			Foot fracture/ left hallux fracture (first toe)	1	09SEP2020	17/42	2	No	O	NA/TC/TCN	R (20OCT2020)	N/N
>55/ C459100 1 1133 11331237	3^	GENRL	Injection site pain/ PAIN INJECTION SITE (LEFT ARM)	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11133 11331244	3^	GENRL	Pain/ Body Ache	1	07SEP2020	13/1	2	No	O	NA/TC	R (07SEP2020)	N/N
>55/ C459100 11133 11331251	3^	GENRL	Chills/ Chills	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
			Injection site discomfort/ Discomfort at injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
			Pain/ body aches	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Arthralgia/ joint pain	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 11133 11331279	3^	GENRL	Fatigue/ FATIGUE	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 11133 11331281	3^	GENRL	Fatigue/ TIREDNESS	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Chills/ chills	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Fatigue/ tiredness	2	18SEP2020	1/6	1	Yes		NA/TCN	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1133 11331290	3^	GENRL	Pain/ body aches	2	18SEP2020	1/4	2	Yes		NA/TC/TCN	R (21SEP2020)	N/N	
			NERV	Headache/ headches	2	18SEP2020	1/2	2	Yes		NA/TC/TCN	R (19SEP2020)	N/N
			GENRL	Malaise/ Malaise	1	29AUG2020	3/3	2	Yes		NA/TC	R (31AUG2020)	N/N
			NERV	Headache/ Headache	1	29AUG2020	3/3	2	Yes		NA/TC	R (31AUG2020)	N/N
			GENRL	Chills/ CHILLS	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			NERV	Pain/ BODY ACHES	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1133 11331302	3^	GENRL	Headache/ HEADACHE	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
			GENRL	Pain/ Body ache	1	27AUG2020	1/7	1	Yes		NA	R (02SEP2020)	N/N
			GENRL	Fatigue/ FATIGUE	2	18SEP2020	1/5	1	Yes		NA/TCN	R (22SEP2020)	N/N
>55/ C459100 1 1133 11331312	3^	INFEC	Pain/ BODY ACHES	2	18SEP2020	1/5	2	Yes		NA/TC/TCN	R (22SEP2020)	N/N	
			Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION (URI)	2	01OCT2020	14/5	1	No	O	NA	R (05OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1133 11331344	3^	PSYCH	Anxiety disorder/ Worsening of Anxiety Disorder	1	08SEP2020	11/1	2	No	O	NA	R (08SEP2020)	N/N
		RESP	Dyspnoea/ shortness of breath	1	08SEP2020	11/1	1	No	O	NA	R (08SEP2020)	N/N
>55/ C459100 1 1133 11331392	3^	NERV	Headache/ HEADACHE	1	08SEP2020	7/2	1	No	O	NA/TC/TCN	R (09SEP2020)	N/N
		MUSC	Musculoskeletal stiffness/ LEFT SIDE NECK STIFFNESS	1	13SEP2020	12/13	1	No	O	NA/TC/TCN	R (25SEP2020)	N/N
>55/ C459100 1 1133 11331412	3^	GENRL	Chills/ Chills	2	30SEP2020	1/5	1	Yes		NA	R (04OCT2020)	N/N
			Injection site pain/ Pain at Injection site (Left arm)	2	30SEP2020	1/5	1	Yes		NA	R (04OCT2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	1/5	2	Yes		NA/TC/TCN	R (04OCT2020)	N/N
>55/ C459100 1 1133 11331415	3^	GASTR	Diarrhoea/ DIARRHEA	1	11SEP2020	3/2	1	Yes		NA	R (12SEP2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA	2	02OCT2020	3/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100	3^	GENRL	Chills/ CHILLS	2	16OCT2020	3/3	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1133 11331453			Pyrexia/ FEVER	2	16OCT2020	3/3	1	Yes		NA	R (18OCT2020)	N/N
>55/ C459100 1 1133 11331459	3^	GENRL	Fatigue/ FATIGUE	2	10OCT2020	2/2	2	Yes		NA/TC	R (11OCT2020)	N/N
>55/ C459100 1 1133 11331471	3^	GENRL	Fatigue/ FATIGUE	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ PAIN INJECTION SITE (LEFT UPPER ARM)	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1133 11331503	3^	GENRL	Pyrexia/ Fever	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 1134 11341002	3^	BLOOD	Iron deficiency anaemia/ Iron Deficiency Anemia	1	18AUG2020	13/8	2	No	O	NA	R (25AUG2020)	N/N
>55/ C459100 1 1134 11341011	3^	INJ&P	Sunburn/ Sunburn Bilateral Forearms	1	18AUG2020	12/8	1	No	O	NA	R (25AUG2020)	N/N
>55/ C459100	3^	METAB	Dehydration/ Dehydration	2	02SEP2020	3/9	2	No	O	NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1134 11341016 >55/ C459100 1 1134 11341024	3^	INJ&P	Fall/ Fall	1	18AUG2020	9/1	2	No	O	NA	R (18AUG2020)	N/N
		MUSC	Arthralgia/ left knee pain	1	18AUG2020	9/15	2	No	O	NA	R (01SEP2020)	N/N
		METAB	Gout/ GOUT	2	14SEP2020	14/8	2	No	O	NA/TC	R (21SEP2020)	N/N
			Vitamin D deficiency/ VITAMIN D DEFICIENCY	2	14SEP2020	14/57	2	No	O	NA/TC	R (09NOV2020)	N/N
>55/ C459100 1 1134 11341035	3^	MUSC	Back pain/ WORSENING OF BACK PAIN	2	02SEP2020	2/61	2	No	O	NA/TC	R (01NOV2020)	N/N
>55/ C459100 1 1134 11341037	3^	INJ&P	Contusion/ CONTUSION ON HEAD	1	26AUG2020	16/29	1	No	O	NA	R (23SEP2020)	N/N
		NERV	Headache/ HEADACHE	1	26AUG2020	16/C	1	No	O	NA	N	N/N
		CARD	Palpitations/ PALPITATIONS	2	30SEP2020	30/8	2	No	O	NA	R (07OCT2020)	N/N
		SKIN	Night sweats/ NIGHT SWEATS	2	30SEP2020	30/8	2	No	O	NA	R (07OCT2020)	N/N
		VASC	Hypertension/ HYPERTENSION	2	30SEP2020	30/8	1	No	O	NA/TC	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11134 11341042	3^	GASTR	Diarrhoea/ Loose stool	2	07SEP2020	7/1	1	Yes		NA	R (07SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	08NOV2020	69/2	1	No	O	NA	R (09NOV2020)	N/N
>55/ C459100 11134 11341044	3^	MUSC	Arthralgia/ Right Hip Pain	1	01SEP2020	21/11	2	No	O	NA	R (11SEP2020)	N/N
>55/ C459100 11134 11341045	3^	MUSC	Arthralgia/ Pain to left elbow	1	24AUG2020	13/23	1	No	O	NA	RS (15SEP2020)	N/N
>55/ C459100 11134 11341058	3^	GASTR	Intestinal obstruction/ Intestinal Obstruction	1	20AUG2020	9/15	3	No	O	NA/TCN	R (03SEP2020)	Y/N
>55/ C459100 11134 11341115	3^	MUSC	Myalgia/ left arm muscle pain	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
>55/ C459100 11134 11341145	3^	NERV	Dizziness/ Dizziness	2	05OCT2020	25/5	1	No	O	NA	R (09OCT2020)	N/N
		RESP	Sinus pain/ Sinus Pain	2	05OCT2020	25/C	1	No	O	NA	RG	N/N
>55/ C459100	3^	GASTR	Toothache/ right upper side tooth ache	1	27AUG2020	3/62	2	No	O	NA/TC	R (27OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1134 11341161 >55/ C459100 1 1134 11341181	3^	GENRL	Pain/ Body Aches	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		VASC	Hypertension/ Worsening Hypertension	2	04OCT2020	19/3	2	No	O	NA/TC	R (06OCT2020)	N/N
>55/ C459100 1 1134 11341185	3^	INFEC	Urinary tract infection/ urinary tract infection	1	09SEP2020	15/5	1	No	O	NA/TC	R (13SEP2020)	N/N
>55/ C459100 1 1134 11341250	3^	NEOPL	Adrenal gland cancer/ ADRENAL ADENOCARCINOMA	2	20OCT2020	27/C	4	No	O	NA/TC	N	Y/N
>55/ C459100 1 1134 11341309	3^	GASTR	Nausea/ nausea	1	02OCT2020	24/2	2	No	O	NA	R (03OCT2020)	N/N
>55/ C459100 1 1134 11341342	3^	GENRL	Chills/ Chills	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
			Pain/ Body Aches	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100	3^	NERV	Headache/ intermittent headaches	1	17SEP2020	2/36	2	No	O	NA/TC	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1134 11341353		INFEC	Sinusitis/ sinus infection	1	23SEP2020	8/30	1	No	O	NA	R (22OCT2020)	N/N
		GENRL	Chills/ chills	2	05NOV2020	2/C	2	Yes		NA	RG	N/N
		NERV	Headache/ headache	2	05NOV2020	2/C	2	Yes		NA	RG	N/N
>55/ C459100 1 1134 11341367	3^	INFEC	Gingivitis/ lower right gum infection	2	22OCT2020	10/11	2	No	O	NA/TC	R (01NOV2020)	N/N
>55/ C459100 1 1134 11341388	3^	GASTR	Diarrhoea/ DIARRHEA	1	20OCT2020	13/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1135 11351003	3^	VASC	Haematoma/ hematoma (right arm - antecubital)	1	10AUG2020	8/3	1	No	O	NA	R (12AUG2020)	N/N
>55/ C459100 1 1135 11351031	3^	GASTR	Toothache/ toothache - right upper molar	1	23AUG2020	19/9	1	No	O	NA/TC	R (31AUG2020)	N/N
>55/ C459100 1 1135 11351032	3^	INJ&P	Joint dislocation/ right shoulder dislocation	1	20AUG2020	16/2	1	No	O	NA	R (21AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Osteopenia/ Osteopenia	1	21AUG2020	17/C	1	No	O	NA	N	N/N
>55/ C459100 1 1135 11351033	3^	NERV	Hypoaesthesia/ numbness on the back of the head	2	04SEP2020	9/31	1	No	O	NA	R (04OCT2020)	N/N
>55/ C459100 1 1135 11351045	3^	INFEC	Cellulitis/ right lower limb cellulitis	2	04OCT2020	41/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1135 11351064	3^	NERV	Paraesthesia/ tingling sensation - bilateral shoulders	1	24AUG2020	18/8	1	No	O	NA	R (31AUG2020)	N/N
>55/ C459100 1 1135 11351079	3^	GASTR	Tongue ulceration/ tongue ulcers	1	10AUG2020	3/3	1	Yes		NA	R (12AUG2020)	N/N
		RESP	Throat irritation/ scratchy throat	1	10AUG2020	3/3	1	Yes		NA	R (12AUG2020)	N/N
		MUSC	Arthralgia/ knee pain - bilateral	1	20AUG2020	13/2	1	Yes		NA	R (21AUG2020)	N/N
>55/ C459100 1 1135 11351098	3^	INJ&P	Limb injury/ thumb on left hand injured	2	07SEP2020	8/8	1	No	O	NA/TC	R (14SEP2020)	N/N
>55/ C459100 1 1135 11351110	3^	GASTR	Diarrhoea/ diarrhea	2	27SEP2020	28/2	1	No	O	NA	R (28SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11135 11351116	3^	MUSC	Arthralgia/ right hip pain	1	15AUG2020	3/10	1	Yes		NA/TC	R (24AUG2020)	N/N
>55/ C459100 11135 11351135	3^	METAB	Insulin resistance/ worsening of insulin resistance	2	31OCT2020	54/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 11135 11351143	3^	HEPAT	Cholecystitis acute/ acute cholecystitis	2	14OCT2020	36/4	3	No	O	NA/TC/TCN	R (17OCT2020)	Y/N
		INFEC	Urinary tract infection/ urinary tract infection	2	15OCT2020	37/3	1	No	O	NA/TC	R (17OCT2020)	N/N
>55/ C459100 11135 11351147	3^	GENRL	Fatigue/ fatigue	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
			Injection site pain/ injection site pain	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
>55/ C459100 11135 11351153	3^	MUSC	Myalgia/ muscle pain	1	19AUG2020	2/3	1	Yes		NA/TC	R (21AUG2020)	N/N
>55/ C459100 11135 11351182	3^	GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1135 11351218 >55/ C459100	3^	IN FEC	Tooth infection/ infection of left lower tooth #18	2	13OCT2020	27/1	1	No	O	NA/TC/TCN	R (13OCT2020)	N/N
1 1135 11351219 >55/ C459100	3^	GEN RL	Fatigue/ fatigue	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
1 1135 11351223			Injection site pain/ pain at injection site	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
		MUSC	Myalgia/ myalgia	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
>55/ C459100 1 1135 11351232	3^	NER V	Paraesthesia/ paresthesia	1	15SEP2020	16/C	2	No	O	NA	RG	N/N
>55/ C459100 1 1135 11351238	3^	GEN RL	Injection site pain/ soreness right arm injection site	1	31AUG2020	1/8	1	Yes		NA	R (07SEP2020)	N/N
>55/ C459100 1 1135 11351261	3^	GEN RL	Injection site pain/ pain on the injection site - left arm	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		MUSC	Arthralgia/ knee pain - both legs	1	02SEP2020	2/1	1	No	O	NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1135 11351280	3^	GENRL	Pain/ bodyaches	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		GASTR	Diarrhoea/ loose bowel movement	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Chills/ chills	2	25SEP2020	2/C	1	Yes		NA/TC	RG	N/N
			Pyrexia/ Fever	2	25SEP2020	2/C	1	Yes		NA/TC	RG	N/N
>55/ C459100 1 1135 11351312	3^	INV	Heart rate increased/ Increased heart rate	2	25SEP2020	2/1	1	No	O	NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site*		08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 1 1135 11351316	3^	GENRL	Fatigue/ fatigue	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ pain at injection site	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1135 11351321	3^	NERV	Headache/ headache	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ pain at injection site	2	28SEP2020	1/C	2	Yes		NA/TC	RG	N/N
>55/ C459100 1 1135 11351333	3^	EYE	Cataract/ right eye cataract	2	27OCT2020	30/1	1	No	O	NA/TC	R (27OCT2020)	N/N
>55/ C459100 1 1135 11351339	3^	PSYCH	Anxiety/ worsening of anxiety	1	11SEP2020	3/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1135 11351380	3^	GENRL	Pain/ Body Aches	1	19SEP2020	2/3	1	Yes		NA/TC	R (21SEP2020)	N/N
			Pyrexia/ Low grade temperature	1	19SEP2020	2/3	1	Yes		NA/TC	R (21SEP2020)	N/N
>55/ C459100 1 1135 11351409	3^	GENRL	Pyrexia/ fever (low grade)	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
		MUSC	Myalgia/ muscle pain (whole body)	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 1136 11361009	3^	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	10SEP2020	24/12	2	Yes		NA	R (21SEP2020)	N/N
		MUSC	Pain in extremity/ LEFT ARM PAIN	1	10SEP2020	24/28	2	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11136 11361023	3^	INFEC	Genital herpes/ worsening of genital herpes	1	09SEP2020	21/5	1	No	O	NA/TC	R (13SEP2020)	N/N
		INFEC	Hordeolum/ RIGHT EYE STYE	1	17SEP2020	29/38	1	No	O	NA/TC	RS (24OCT2020)	N/N
		SKIN	Skin lesion/ EXACERBATION OF ATYPICAL SKIN LESION RIGHT THIGH- BENIGN	2	SEP2020	1/	1	No	O	NA/TCN	R	N/N
>55/ C459100 11136 11361055	3^	GENRL	Pyrexia/ fever (102.0 F)	2	22SEP2020	1/4	2	No	O	NA/TC	R (25SEP2020)	N/N
>55/ C459100 11139 11391004	2^	GENRL	Injection site erythema/ Erythema Distal to Injection Site	2	20AUG2020	1/1	1	No	O	NA	R (20AUG2020)	N/N
>55/ C459100 11139 11391005	2^	GENRL	Injection site discolouration/ Discoloration at injection site	1	29JUL2020	1/16	1	Yes		NA	R (13AUG2020)	N/N
>55/ C459100 11139 11391009	2^	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	20OCT2020	62/C	1	No	O	NA/TC	RG	N/N
			Type 2 diabetes mellitus/ Type 2 Diabetes	2	20OCT2020	62/C	1	No	O	NA	RG	N/N
>55/ C459100	3^	GENRL	Injection site bruising/ Injection site bruising	1	31JUL2020	1/16	2	Yes		NA	R (15AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1139 11391026 >55/ C459100	3^	SKIN	Dermatitis contact/ Poison ivy- lower extremities	1	16AUG2020	14/C	2	No	O	NA/TC/TCN	RG	N/N
1 1139 11391034 >55/ C459100	3^	NERV	Paraesthesia/ Tingling in left arm	1	05AUG2020	1/1	1	Yes		NA	R (05AUG2020)	N/Y
1 1139 11391045 >55/ C459100	3^	INJ&P	Fall/ Accidental Fall	2	14SEP2020	20/1	2	No	O	NA	R (14SEP2020)	N/N
1 1139 11391055			Foot fracture/ Fractured fourth and fifth metatarsal	2	14SEP2020	20/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1139 11391068	3^	BLOOD	Lymphadenopathy/ Left Axillary lymph node swelling	1	13AUG2020	8/4	1	Yes		NA	R (16AUG2020)	N/N
>55/ C459100 1 1140 11401002	2^	CARD	Coronary artery dissection/ Spontaneous coronary artery dissection	2	28AUG2020	12/1	4	No	O	NA	R (28AUG2020)	Y/N
		UNC	MYOCARDIAL ISCHEMIA-RELATED TO SPONTANEOUS CORONARY ARTERY DISSECTION@@/ Myocardial Ischemia- Related to	2	28AUG2020	12/1	1	No	O	NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1140 11401035	3^	SKIN	spontaneous coronary artery dissection Urticaria/ urticaria	1	13AUG2020	10/1	2	No	O	P/TC/W	R (13AUG2020)	N/N
>55/ C459100 1 1140 11401036	3^	GENRL	Pyrexia/ Fever	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	10SEP2020	3/1	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10SEP2020	3/1	1	Yes		NA	R (10SEP2020)	N/N
			Pain/ Body Aches	2	10SEP2020	3/1	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1140 11401041	3^	INJ&P	Muscle strain/ muscle strain L hip	1	11AUG2020	7/C	2	No	O	NA	N	N/N
>55/ C459100 1 1140 11401043	3^	EAR	Ear pain/ Bilateral Otalgia	1	19AUG2020	15/C	1	No	O	NA	N	N/N
>55/ C459100 1 1140 11401047	3^	VASC	Hypertension/ hypertension	1	05AUG2020	1/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Musculoskeletal pain/ Left Buttock Pain	1	23AUG2020	19/C	1	No	O	NA	N	N/N
>55/ C459100 1 1140 11401078	3^	HEPAT	Cholecystitis acute/ Acute Cholecystitis	2	16SEP2020	20/15	4	No	O	NA/TC	R (30SEP2020)	Y/N
>55/ C459100 1 1140 11401082	3^	INJ&P	Arthropod sting/ Bee-Sting	1	10AUG2020	4/1	2	No	O	NA/TC	R (10AUG2020)	N/N
>55/ C459100 1 1140 11401104	3^	MUSC	Back pain/ Low Back Pain	1	18AUG2020	6/1	1	No	O	NA	R (18AUG2020)	N/N
>55/ C459100 1 1140 11401133	3^	VASC	Phlebitis/ phlebitis*		17AUG2020	1/22	1	No	O	NA/TC	R (07SEP2020)	N/N
>55/ C459100 1 1140 11401145	3^	GENRL	Injection site pain/ pain at injection site	1	18AUG2020	1/2	2	Yes		NA/TC	R (19AUG2020)	N/N
>55/ C459100 1 1140 11401146	3^	GENRL	Fatigue/ fatigue	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	12SEP2020	4/2	2	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1140 11401155		MUSC	Myalgia/ Muscle Aches	2	12SEP2020	4/2	2	Yes		NA	R (13SEP2020)	N/N
>55/ C459100 1 1140 11401173	3^	GENRL	Pyrexia/ fever	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C459100 1 1140 11401179	3^	GENRL	Injection site pain/ pain at injection site	2	14SEP2020	1/4	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C459100 1 1140 11401182	3^	INV	Body temperature decreased/ Low Temperature	1	14SEP2020	22/1	1	No	O	NA	R (14SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1140 11401185	3^	INFEC	Sinusitis/ Sinus Infection	1	25AUG2020	2/16	2	No	O	NA	R (09SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ Fever	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Generalized Myalgias	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		PSYCH	Insomnia/ Insomnia	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 11140 11401194	3^	GENRL	Injection site pain/ pain at injection site	1	26AUG2020	1/7	1	Yes		NA	R (01SEP2020)	N/N
		GASTR	Diarrhoea/ loose stool	1	29AUG2020	4/1	1	Yes		NA	R (29AUG2020)	N/N
		MUSC	Myalgia/ Left arm muscular pain	1	29AUG2020	4/1	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 11140 11401197	3^	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
			Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 11140 11401213	3^	GENRL	Injection site pain/ Pain at Injection Site	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 11140 11401222	3^	GENRL	Injection site pain/ Pain at injection site	1	31AUG2020	1/2	2	Yes		NA/TC	R (01SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1140 11401230	3^	GENRL	Injection site pain/ Pain at injection site	2	21SEP2020	1/1	2	Yes		NA/TC	R (21SEP2020)	N/N
		NERV	Headache/ headache	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1140 11401235	3^	GENRL	Injection site pain/ pain at injection site	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
>55/ C459100 1 1140 11401236	3^	GENRL	Injection site pain/ Pain at injection site	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
		GENRL	Chills/ chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1140 11401237	3^		Fatigue/ fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Pain in extremity/ Left arm soreness	2	24SEP2020	2/5	2	Yes		NA/TC	R (28SEP2020)	N/N
		MUSC	Pain in extremity/ Pain in upper right arm	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11140 11401238	3^	MUSC	Pain in extremity/ Pain in upper R arm	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		SKIN	Night sweats/ Night Sweats	2	25SEP2020	2/C	1	Yes		NA	RG	N/N
>55/ C459100 11140 11401244	3^	GASTR	Gastrointestinal pain/ Worsening GI Cramping	1	08SEP2020	7/13	3	No	O	NA	R (20SEP2020)	N/N
>55/ C459100 11140 11401247	3^	VASC	Small intestinal obstruction/ Small Bowel Obstruction	1	08SEP2020	7/13	3	No	O	NA	R (20SEP2020)	Y/N
			Hypertension/ hypertension*		02SEP2020	1/C	2	No	O	NA/TC	N	N/N
>55/ C459100 11140 11401254	3^	MUSC	Pain in extremity/ Sore Arm-LEFT	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Malaise/ general malaise	2	23SEP2020	2/2	2	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Myalgia/ generalized myalgias	2	23SEP2020	2/2	2	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ headache	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11140 11401268	3^	GENRL	Injection site pain/ pain at injection site	1	08OCT2020	1/4	1	Yes		NA/TC	R (11OCT2020)	N/N
>55/ C459100 11140 11401276	3^	GENRL	Asthenia/ Weakness	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
			Injection site pain/ Pain at injection site	1	09OCT2020	1/2	2	Yes		NA	R (10OCT2020)	N/N
		NERV	Headache/ Headache	1	09OCT2020	1/2	2	Yes		NA	R (10OCT2020)	N/N
>55/ C459100 11141 11411001	2^	SKIN	Macule/ Skin Macule on left upper arm	1	06AUG2020	8/11	1	Yes		NA	R (16AUG2020)	N/N
>55/ C459100 11141 11411028	3^	MUSC	Back pain/ Back Pain	2	27AUG2020	2/21	3	Yes		NA	R (16SEP2020)	N/N
		GENRL	Face oedema/ Facial edema	2	01SEP2020	7/2	1	No	O	NA	R (02SEP2020)	N/N
		SKIN	Papule/ skin papules	2	01SEP2020	7/3	1	No	O	NA	R (03SEP2020)	N/N
		SKIN	Rash maculo-papular/ Maculopapular rash	2	26OCT2020	62/C	3	No	O	NA/TC	N	N/N
		GASTR	Diarrhoea/ Loose stools	2	27OCT2020	63/C	1	No	O	NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11141 11411100	3^	GENRL	Injection site pain/ Tenderness at injection site	2	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site erythema/ Erythema at injection site	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
			Injection site swelling/ Swelling at injection site	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 11141 11411101	3^	GENRL	Injection site pain/ injection site soreness	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N
>55/ C459100 11141 11411105	3^	GENRL	Injection site plaque/ skin plaque injection area left upper extremity	1	20AUG2020	2/21	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 11141 11411111	3^	GENRL	Injection site pain/ injection pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/Y
		GENRL	Fatigue/ Fatigue	2	12SEP2020	2/3	3	Yes		NA	R (14SEP2020)	N/N
			Injection site pain/ Injection site pain	2	12SEP2020	2/C	2	Yes		NA/TC	RG	N/N
		MUSC	Arthralgia/ Bilateral Knee Arthralgia	2	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11141 11411134	3^	NERV GENRL	Pain in extremity/ Leg Aches Bilateral	2	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N
			Headache/ Headache	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
			Injection site pain/ injection site pain	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
>55/ C459100 11141 11411143	3^	GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 11141 11411147	3^	NERV GENRL	Fatigue/ Fatigue	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Headache/ Headache	2	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
			Injection site pain/ Injection site soreness left arm	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/Y
>55/ C459100 11141 11411155	3^	GENRL	Injection site pain/ arm pain at injection site	1	01SEP2020	2/2	2	Yes		NA	R (02SEP2020)	N/N
		MUSC	Pyrexia/ fever	1	01SEP2020	2/2	2	Yes		NA	R (02SEP2020)	N/N
			Myalgia/ myalgias	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11141 11411157	3^	NERV	Headache/ headache	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ Chills	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgia Generalized	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C459100 11141 11411160	3^	GENRL	Injection site pain/ injection site pain left	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		MUSC	Myalgia/ diffuse arm myalgia	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Pyrexia/ low grade fever	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 11141 11411183	3^	GENRL	Injection site bruising/ bruise at injection site	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/Y
			Injection site pain/ injection site pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/Y
		GENRL	Pyrexia/ low grade fever	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11141 11411189	3^	MUSC	Arthralgia/ arthralgia	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Pyrexia/ Low Grade Fever	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Arthralgia/ Arthralgia	2	30SEP2020	2/2	1	Yes		NA/TCN	R (01OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	3/1	1	Yes		NA/TC	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	01OCT2020	2/3	2	Yes		NA/TC	R (03OCT2020)	N/N
			Malaise/ Malaise	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
			Pyrexia/ Low grade Fever	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 11141 11411191	3^	INJ&P	Vaccination complication/ Range of upward motion decreased in Vaccinated arm	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	01OCT2020	1/5	1	Yes		NA	R (05OCT2020)	N/N
		GASTR	Nausea/ Nausea	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11141 11411200	3^	NERV	Headache/ Headache	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Injection site pain/ injection pain site soreness	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Injection site swelling/ injection site swelling	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		INV	Body temperature increased/ elevated body temperature	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		NERV	Dizziness/ Dizziness	1	14SEP2020	4/1	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Tenderness/Pain	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Pyrexia/ Fever (Tmax 101.2)	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 11141 11411207	3^	NERV	Headache/ Headache	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
		GASTR	Vomiting/ Emesis	2	08OCT2020	2/1	1	No	O	NA	R (08OCT2020)	N/N
>55/ C459100 11141 11411216	3^	GENRL	Injection site pain/ injection site soreness left arm	1	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Soreness	2	07OCT2020	1/2	1	Yes		NA/TC	R (08OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11141 11411232	3^	GENRL	Injection site pain/ tenderness at injection site	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
			Malaise/ Malaise	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
			Pain/ Body aches	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
>55/ C459100 11141 11411233	3^	GENRL	Chills/ Chills	1	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
			Fatigue/ Fatigue ¹⁹	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
			Injection site pain/ Injection site pain left arm	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ Myalgia back area	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ Headache	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Soreness	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
		NERV	Headache/ Headache	2	14OCT2020	6/1	2	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 11141 11411244	3^	GENRL	Fatigue/ Fatigue	1	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N	
		RESP	Oropharyngeal pain/ Sore Throat	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
		GENRL	Chills/ Chills	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N	
				2	16OCT2020	2/2	3	Yes	NA/TC	R (17OCT2020)	N/N		
				Injection site pain/ Injection Site Pain Left Arm	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N
				Pyrexia/ Fever	2	16OCT2020	2/2	3	Yes		NA/TC	R (17OCT2020)	N/N
		INV	Body temperature increased/ Elevated Body Temperature	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N	
		MUSC	Myalgia/ Generalized Myalgias	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N	
				2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N	
				Myalgia/ Muscle Aches	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N
		Headache/ Headache	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N		
>55/ C459100 11141 11411253	3^	MUSC	Muscle spasms/ Back Spasms	1	17OCT2020	11/9	3	No	O	NA/TC/TCN	R (25OCT2020)	N/N	
>55/ C459100	3^	VASC	Orthostatic hypotension/ Possible postural hypotension	2	31AUG2020	4/1	4	No	O	NA/TC	R (31AUG2020)	Y/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1142 11421032 >55/ C459100	3^	GASTR	Colitis/ Colitis	2	05SEP2020	8/C	3	No	O	NA/TC	RG	Y/N
1 1142 11421044 >55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	03SEP2020	7/2	1	Yes		NA	R (04SEP2020)	N/N
1 1142 11421061		NERV	Headache/ Headache	2	03SEP2020	7/2	2	Yes		NA	R (04SEP2020)	N/N
		UNC	GENERALIZED JOINT PAIN@@/ Generalized Joint pain	2	03SEP2020	7/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 1 1142 11421104	3^	NERV	Tension headache/ tension headache	1	14AUG2020	1/2	3	No	O	NA/TC	R (15AUG2020)	N/Y
>55/ C459100 1 1142 11421111	3^	GASTR	Abdominal pain/ Abdominal Pain	1	26AUG2020	10/41	2	Yes		P	R (05OCT2020)	N/N
		SKIN	Night sweats/ Night sweats	1	29AUG2020	13/C	3	Yes		P	RG	N/N
>55/ C459100 1 1142 11421146	3^	GENRL	Injection site pain/ Injection site pain	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11142 11421148	3^	INJ&P	Muscle strain/ muscle strain of lower leg/calf	2	25SEP2020	12/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 11142 11421177	3^	GENRL	Vaccination site pain/ vaccine site pain (left deltoid)	1	02SEP2020	1/3	1	Yes		NA/TCN	R (04SEP2020)	N/N
		GENRL	Vaccination site pain/ vaccine site pain (left deltoid)	2	24SEP2020	2/3	1	Yes		NA/TC/TCN	R (26SEP2020)	N/N
>55/ C459100 11142 11421227	3^	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
>55/ C459100 11142 11421232	3^	GENRL	Fatigue/ Fatigue	2	07OCT2020	1/4	3	Yes		NA	R (10OCT2020)	N/N
			Injection site pain/ Injection site pain	2	07OCT2020	1/4	3	Yes		NA	R (10OCT2020)	N/N
			Pain/ Body aches	2	07OCT2020	1/4	3	Yes		NA	R (10OCT2020)	N/N
		NERV	Headache/ Headache	2	07OCT2020	1/4	3	Yes		NA	R (10OCT2020)	N/N
>55/ C459100	3^	GENRL	Malaise/ Malaise	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1142 11421243 >55/ C459100	3^	CARD	Ventricular arrhythmia/ Ventricular arrhythmias	2	14OCT2020	1/8	3	Yes		NA/TC	R (21OCT2020)	Y/N
1 1142 11421247 >55/ C459100	3^	GENRL	Injection site pain/ Injection site soreness	1	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
1 1142 11421259		NERV	Headache/ Headache	1	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		NERV	Headache/ Headache	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1145 11451008	3^	GENRL	Pain/ body ache	2	08SEP2020	7/2	1	Yes		NA/TC	R (09SEP2020)	N/N
>55/ C459100 1 1145 11451012	3^	MUSC	Back pain/ back pain	1	16AUG2020	3/16	2	No	O	NA/TCN	R (31AUG2020)	N/N
>55/ C459100 1 1145 11451014	3^	GENRL	Injection site pain/ injection site pain (Left Arm)	2	30SEP2020	29/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11145 11451016	3^	NERV	Headache/ Headache	2	11SEP2020	2/4	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	12SEP2020	3/3	1	Yes		NA	R (14SEP2020)	N/N
>55/ C459100 11145 11451023	3^	GENRL	Asthenia/ Weakness	1	19AUG2020	2/2	2	Yes		NA	R (20AUG2020)	N/N
			Injection site pain/ Injection site pain	1	19AUG2020	2/2	3	Yes		NA/TC	R (20AUG2020)	N/N
>55/ C459100 11145 11451024	3^	GENRL	Injection site pain/ Pain at injection site	1	18AUG2020	1/1	1	Yes		NA	R (18AUG2020)	N/Y
		GENRL	Chills/ chills	2	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N
			Fatigue/ fatigue	2	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N
		MUSC	Arthralgia/ generalized joint pain	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
			Myalgia/ muscle pain	2	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ headache	2	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N
		GENRL	Chills/ chills	2	11SEP2020	4/4	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11145 11451038	3^	GENRL	Injection site pain/ injection site pain	2	11SEP2020	4/4	1	Yes		NA	R (14SEP2020)	N/N
			Injection site swelling/ swelling at injection site left arm	2	11SEP2020	4/4	1	Yes		NA	R (14SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/Y
			Myalgia/ Muscle pain	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C459100 11145 11451041	3^	GENRL	Headache/ Headache	2	15SEP2020	1/4	3	Yes		NA/TC	R (18SEP2020)	N/N
			Injection site pain/ pain at injection site	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/Y
>55/ C459100 11145 11451052	3^	GENRL	Asthenia/ Asthenia (weakness)	2	15SEP2020	1/2	1	Yes		NA/TCN	R (16SEP2020)	N/N
>55/ C459100 11145 11451056	3^	PSYCH	Injection site pain/ left injection site pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
			Insomnia/ Insomnia	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N
			Tachycardia/ tachycardia	2	07OCT2020	21/2	3	No	O	NA	R (08OCT2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		CARD	Pericardial effusion/ small pericardial effusion	2	08OCT2020	22/C	2	No	O	NA	RG	N/N
>55/ C459100 11145 11451061	3^	INJ&P	Limb injury/ LEFT LOWER LEG PAIN (POST-TRAUMATIC)	1	16SEP2020	17/C	2	No	O	NA	RG	N/N
>55/ C459100 11145 11451065	3^	SKIN	Pruritus/ Itching legs	1	06SEP2020	4/1	1	Yes		NA	R (06SEP2020)	N/N
>55/ C459100 11145 11451072	3^	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
			Injection site pain/ Injection site pain	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
>55/ C459100 11145 11451073	3^	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
>55/ C459100 11145 11451076	3^	NERV	Parkinsonism/ parkinsonism	1	18SEP2020	15/C	1	No	O	P	N	N/N
>55/ C459100 11145 11451078	3^	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
			Injection site pain/ Injection site pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11145 11451083	3^	NERV	Headache/ Headache	1	05SEP2020	2/2	1	Yes		NA/TC	R (06SEP2020)	N/N
		MUSC	Musculoskeletal stiffness/ Neck stiffness	1	15SEP2020	12/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		GASTR	Nausea/ NAUSEOUS	1	24SEP2020	21/3	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ headache	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Fatigue/ FATIGUE	2	25SEP2020	2/2	3	Yes		NA	R (26SEP2020)	N/N
		NERV	Dizziness/ DIZZINESS	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
			Injection site swelling/ Injection site swelling	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
			Injection site warmth/ Injection site warmth	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	METAB	Decreased appetite/ Loss of appetite	1	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N	
	VASC	Flushing/ Facial flushing	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Chills/ Chills	1	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11145 11451084	3^	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
			Injection site pain/ injection site pain	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N
			Decreased appetite/ anorexia	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Flushing/ facial flushing	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
			Fatigue/ fatigue	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 11145 11451089	3^	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 11145 11451100	3^	GENRL	Injection site pain/ injection site pain	1	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site erythema/ injection site redness	2	01OCT2020	1/4	1	Yes		NA	R (04OCT2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Left Arm injection site pain	1	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1145 11451102		GENRL	Injection site pain/ injection site pain	2	01OCT2020	1/3	3	Yes		NA	R (03OCT2020)	N/N
		MUSC	Arthralgia/ joint aches	2	02OCT2020	2/2	3	Yes		NA	R (03OCT2020)	N/N
			Myalgia/ muscle aches	2	02OCT2020	2/2	3	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1146 11461005	3^	SURG	Hip surgery/ Excision of cyst of the right hip	2	17SEP2020	18/1	2	No	O	NA/TCN	R (17SEP2020)	N/N
>55/ C459100 1 1146 11461024	3^	GASTR	Faeces soft/ Change in bowel movements - Softer Stool	1	16AUG2020	3/66	1	Yes		NA	R (20OCT2020)	N/N
>55/ C459100 1 1146 11461027	3^	INV	Blood glucose increased/ Increased glucose	2	02OCT2020	19/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1146 11461039	3^	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/8	1	Yes		NA	R (24AUG2020)	N/N
			Injection site erythema/ Redness at injection site	1	17AUG2020	1/8	1	Yes		NA	R (24AUG2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ injection site pain	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/Y

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1146 11461060		GENRL	Injection site pain/ Injection site pain	2	08SEP2020	1/5	1	Yes		NA	R (12SEP2020)	N/Y
>55/ C459100 1 1146 11461062	3^	GENRL	Injection site pain/ injection site pain	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1146 11461064	3^	GENRL	Injection site pain/ injection site pain	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/Y
		GENRL	Fatigue/ Fatigue	2	10SEP2020	3/3	1	Yes		NA	R (12SEP2020)	N/N
			Pain/ Body Aches	2	10SEP2020	3/3	1	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ Fever of 100.3	2	10SEP2020	3/3	1	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	3/3	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1146 11461065	3^	INV	Blood glucose increased/ Increase in blood sugar	1	12SEP2020	24/C	1	No	O	NA	N	N/N
>55/ C459100 1 1146 11461101	3^	INFEC	Hordeolum/ Stye of left eye	2	28SEP2020	15/7	1	No	O	NA/TCN	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11146 11461109	3^	INV	Blood glucose increased/ Increase in baseline blood sugar	1	01SEP2020	8/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 11146 11461152	3^	INJ&P	Chest injury/ Bruised ribs	2	07OCT2020	22/C	1	No	O	NA	N	N/N
			Fall/ Fall off ladder	2	07OCT2020	22/1	1	No	O	NA/TCN	R (07OCT2020)	N/N
>55/ C459100 11146 11461153	3^	GENRL	Chest pain/ Exertional chest pain	2	04OCT2020	19/12	2	No	O	NA	R (15OCT2020)	N/N
>55/ C459100 11146 11461161	3^	RESP	Interstitial lung disease/ Interstitial Pneumonitis	1	09SEP2020	10/1	2	No	O	NA	R (09SEP2020)	Y/N
		RESP	Atelectasis/ Bibasilar Atelectasis on chest xray	1	10SEP2020	11/31	1	No	O	NA	R (10OCT2020)	N/N
>55/ C459100 11146 11461174	3^	INV	Low density lipoprotein increased/ Elevated LDL	2	16OCT2020	24/C	2	No	O	NA/TC	N	N/N
>55/ C459100 11146 11461180	3^	GASTR	Colitis ulcerative/ Ulcerative colitis	2	12OCT2020	22/11	2	No	O	NA/TC	R (22OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11146 11461181	3^	GENRL	Cyst/ Cyst-like mass on back of head	1	07SEP2020	7/4	2	No	O	NA	R (10SEP2020)	N/N
>55/ C459100 11146 11461232	3^	GENRL	Fatigue/ Fatigue	1	05OCT2020	22/3	2	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/ Injection Site pain	2	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/Y
			Pyrexia/ Fever of 101.0F	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/Y
>55/ C459100 11146 11461264	3^	RESP	Pulmonary embolism/ Pulmonary Emboli	2	08NOV2020	26/C	2	No	O	NA/TC	N	Y/N
>55/ C459100 11147 11471009	3^	RESP	Oropharyngeal pain/ sore throat	1	05AUG2020	3/1	1	No	O	NA	R (05AUG2020)	N/N
>55/ C459100 11147 11471062	3^	EYE	Eye pain/ bilateral eye pain	1	11AUG2020	5/2	1	No	O	NA/TC	R (12AUG2020)	N/N
		INV	Blood triglycerides increased/ Elevated triglycerides	2	14SEP2020	18/C	1	No	O	NA/TCN	N	N/N
>55/ C459100 11147 11471086	3^	SKIN	Dermatitis contact/ allergic contact dermatitis caused by clothing irritation on sensitive skin in lower right abdomen	1	17AUG2020	8/8	1	No	O	NA/TC	R (24AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1147 11471091	3^	NEOPL	Seborrhoeic keratosis/ inflamed seborrheic keratosis	1	18AUG2020	9/1	1	No	O	NA/TCN	R (18AUG2020)	N/N
		METAB	Iron deficiency/ iron deficiency	1	13AUG2020	3/C	1	No	O	NA	N	N/N
>55/ C459100 1 1147 11471106	3^	MUSC	Exostosis/ Bone spur on right knuckle index finger	2	14SEP2020	13/18	1	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1147 11471108	3^	EAR	Ear discomfort/ ear fullness	2	01OCT2020	30/C	1	No	O	NA/TC/TCN	N	N/N
		INV	Blood urea increased/ Elevated BUN	2	01OCT2020	30/C	1	No	O	NA	N	N/N
			Mean cell haemoglobin decreased/ decreased mean corpuscular hemoglobin concentrate	2	01OCT2020	30/C	1	No	O	NA	N	N/N
			Mean cell volume increased/ elevated mean corpuscular hemoglobin	2	01OCT2020	30/C	1	No	O	NA	N	N/N
			Mean cell volume increased/ elevated mean corpuscular volume	2	01OCT2020	30/C	1	No	O	NA	N	N/N
		RESP	Oropharyngeal pain/ sore throat	2	01OCT2020	30/C	1	No	O	NA/TC/TCN	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11147 11471124	3^	NERV	Dizziness/ dizziness	1	17AUG2020	4/1	1	No	O	NA	RS (17AUG2020)	N/N
>55/ C459100 11147 11471200	3^	RESP	Nasal congestion/ Nasal Congestion	1	31AUG2020	4/C	1	No	O	NA	N	N/N
			Oropharyngeal pain/ Sore throat	1	31AUG2020	4/C	1	No	O	NA	N	N/N
			Paranasal sinus hypersecretion/ Cough r/t Sinus drainage	1	31AUG2020	4/C	1	No	O	NA	N	N/N
>55/ C459100 11147 11471208	3^	GASTR	Inguinal hernia/ Left inguinal hernia (exacerbation)	2	08OCT2020	17/C	1	No	O	NA	N	N/N
>55/ C459100 11147 11471221	3^	INFEC	Hordeolum/ Stye on left eyelid	1	09SEP2020	7/C	1	No	O	NA	N	N/N
>55/ C459100 11147 11471239	3^	INV	High density lipoprotein increased/ Increased HDL (95)	1	18SEP2020	9/C	1	No	O	NA	N	N/N
		REPRO	Ovarian mass/ Ovarian Mass	1	21SEP2020	12/C	2	No	O	NA/TCN	RG	Y/N
		INV	Blood chloride decreased/ Decreased Chloride (94)	1	24SEP2020	15/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Blood sodium decreased/ Decreased Sodium (131)	1	24SEP2020	15/C	1	No	O	NA	N	N/N
			Urine ketone body present/ Trace Ketones (Urinalysis)	1	24SEP2020	15/C	1	No	O	NA	N	N/N
			White blood cells urine positive/ Trace Leukocytes in Urinalysis	1	24SEP2020	15/C	1	No	O	NA	N	N/N
		GASTR	Abdominal pain lower/ Left Lower Quadrant Pain	1	25SEP2020	16/C	1	No	O	NA/TCN	N	N/N
>55/ C459100 11149 11491041	3^	GENRL	Pain/ body aches	1	18AUG2020	8/2	1	Yes		NA	R (19AUG2020)	N/N
		NERV	Headache/ Headaches	1	18AUG2020	8/2	1	Yes		NA	R (19AUG2020)	N/N
>55/ C459100 11149 11491080	3^	GENRL	Injection site pain/ left arm injection site pain with motion	2	08SEP2020	1/8	1	Yes		NA	R (15SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	09SEP2020	2/6	1	Yes		NA	R (14SEP2020)	N/N
>55/ C459100 11149 11491090	3^	GENRL	Chills/ chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Pyrexia/ fever	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
>55/ C459100	3^	GENRL	Fatigue/ fatigue	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1149 11491102		MUSC	Myalgia/ muscle aches	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1149 11491131	3^	MUSC	Myalgia/ muscle aches	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N
			Pain in extremity/ left arm soreness	1	24AUG2020	1/5	1	Yes		NA	R (28AUG2020)	N/N
>55/ C459100 1 1149 11491132	3^	GENRL	Chills/ chills	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
		MUSC	Pain in extremity/ left arm pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
>55/ C459100 1 1149 11491134	3^	NERV	Headache/ Headache*		24AUG2020	1/4	1	Yes		NA	R (27AUG2020)	N/N
			Paraesthesia/ Right Arm Paresthesia*		24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
		NERV	Headache/ headache	2	14SEP2020	1/4	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ left arm pain at injection site	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1149 11491138		GASTR	Abdominal distension/ bloating	1	14SEP2020	21/1	1	No	O	NA	R (14SEP2020)	N/N
			Nausea/ nausea	1	14SEP2020	21/1	1	No	O	NA	R (14SEP2020)	N/N
		MUSC	Myalgia/ myalgia	2	29SEP2020	15/5	1	No	O	NA	R (03OCT2020)	N/N
>55/ C459100 1 1149 11491139	3^	GENRL	Fatigue/ fatigue	1	14SEP2020	21/1	1	No	O	NA	R (14SEP2020)	N/N
			Pain/ body aches	1	14SEP2020	21/1	1	No	O	NA	R (14SEP2020)	N/N
			Pyrexia/ fever	1	14SEP2020	21/1	1	No	O	NA/TC	R (14SEP2020)	N/N
>55/ C459100 1 1149 11491152	3^	MUSC	Pain in extremity/ Left arm pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
>55/ C459100 1 1149 11491153	3^	MUSC	Myalgia/ Myalgia	2	19SEP2020	4/2	1	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ Headaches	2	19SEP2020	4/2	1	Yes		NA	R (20SEP2020)	N/N
		RESP	Nasal congestion/ Nasal Congestion	2	02OCT2020	17/4	1	No	O	NA	R (05OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11149 11491168	3^	MUSC	Pain in extremity/ Left arm pain	1	28AUG2020	1/4	1	Yes		NA	R (31AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
		PSYCH	Insomnia/ Increased Insomnia	2	19SEP2020	2/8	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 11149 11491184	3^	GENRL	Fatigue/ fatigue	1	06SEP2020	5/5	1	Yes		NA	R (10SEP2020)	N/N
			Malaise/ malaise	1	06SEP2020	5/5	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ headache	1	06SEP2020	5/5	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 11149 11491193	3^	GENRL	Injection site pain/ right arm pain with touch at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
>55/ C459100 11149 11491200	3^	MUSC	Pain in extremity/ left arm pain	1	05SEP2020	2/7	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
			Fatigue/ Fatigue	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
			Injection site pain/ Tenderness in Left arm (injection site)	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
			Pyrexia/ Fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		MUSC	Myalgia/ Diffuse muscle aching	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
			Pain in extremity/ left arm pain	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ Headache	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
>55/ C459100 1 1149 11491214	3^	GENRL	Fatigue/ fatigue & lassitude	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1149 11491222	3^	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1149 11491237	3^	GENRL	Injection site pain/ Left Arm Pain at injection site	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1149 11491239	3^	UNC	RIGHT ARM PAIN WITH MOTION@@/ Right arm pain with motion	1	22SEP2020	8/4	1	Yes		NA	R (25SEP2020)	N/N
		UNC	SWOLLEN LYMPH NODE IN RIGHT AXILLA@@/ Swollen lymph node in right axilla	1	05OCT2020	21/8	1	No	O	NA/TC	R (12OCT2020)	N/N
>55/ C459100 1 1149 11491251	3^	MUSC	Pain in extremity/ Left arm pain	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Chills/ chills	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
			Pyrexia/ fever	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
>55/ C459100 1 1149 11491257	3^	GENRL	Chills/ chills	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
			Injection site pain/ Left arm pain at injection site	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
			Pyrexia/ fever	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
		NERV	Headache/ headache	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11149 11491260	3^	MUSC	Neck pain/ Cervicalgia	1	21SEP2020	4/3	1	Yes		NA	R (23SEP2020)	N/N
		INFEC	Otitis externa/ Right otitis externa	1	30SEP2020	13/4	1	No	O	NA	R (03OCT2020)	N/N
		INFEC	Otitis externa/ Right otitis externa	1	04OCT2020	17/C	1	No	O	NA	N	N/N
>55/ C459100 11149 11491264	3^	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ Left arm pain at injection site	1	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
			Injection site pain/ Left arm pain at injection site	2	12OCT2020	1/1	1	Yes		NA/TC	R (12OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
>55/ C459100 11149 11491288	3^	GENRL	Injection site pain/ pain at injection site (arm)	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		PSYCH	Insomnia/ insomnia	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ body aches/ myalgia	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ headache	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 11149 11491298	3^	GENRL	Injection site pain/ right arm injection site pain	1	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 11149 11491301	3^	GENRL	Injection site pain/ left arm injection site pain	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
			Pyrexia/ fever	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	27SEP2020	4/3	1	Yes		NA	R (29SEP2020)	N/N
			Injection site pain/ Injection site pain with touch & motion in deltoid muscles	1	27SEP2020	4/3	1	Yes		NA	R (29SEP2020)	N/N
>55/ C459100 11149 11491309	3^	GENRL	Injection site pain/ Right arm pain at injection site with motion	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
			Pyrexia/ Low grade fever 100.5	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 11149 11491313	3^	RESP	Cough/ severe cough	2	01NOV2020	18/C	3	No	O	NA	RG	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11149 11491317	3^	GENRL	Injection site pain/ Pain (with movement) in left arm at injection site	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 11149 11491319	3^	GENRL	Injection site pain/ Injection site pain with touch in left arm	1	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N
>55/ C459100 11149 11491326	3^	GENRL	Injection site pain/ left arm injection site pain	1	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
>55/ C459100 11152 11521013	3^	METAB	Hypercholesterolaemia/ hypercholesterolemia diagnosed	2	28SEP2020	27/C	1	No	O	NA/TC	N	N/N
>55/ C459100 11152 11521092	3^	GASTR	Diarrhoea/ diarrhea	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
			Vomiting/ vomiting	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 11152 11521095	3^	RENAL	Pollakiuria/ urinary frequency	2	06OCT2020	27/27	1	No	O	NA	R (01NOV2020)	N/N
		PSYCH	Bipolar disorder/ worsening of bipolar disorder	2	29OCT2020	50/9	3	No	O	NA/TC	R (06NOV2020)	Y/N
		RESP	Cough/ cough	2	03NOV2020	55/4	1	No	O	NA	R (06NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1152 11521123	3^	GASTR	Diarrhoea/ diarrhea	1	21AUG2020	2/15	2	Yes		NA/TC	R (04SEP2020)	N/N
		GENRL	Chills/ chills	1	21AUG2020	2/15	2	Yes		NA	R (04SEP2020)	N/N
			Fatigue/ fatigue	1	21AUG2020	2/24	2	Yes		NA	R (13SEP2020)	N/N
		NERV	Headache/ headache	1	21AUG2020	2/15	2	Yes		NA/TC	R (04SEP2020)	N/N
		MUSC	Arthralgia/ bilateral hip pain	2	08OCT2020	29/2	1	No	O	NA	R (09OCT2020)	N/N
			Arthralgia/ bilateral knee pain	2	08OCT2020	29/2	1	No	O	NA	R (09OCT2020)	N/N
>55/ C459100 1 1152 11521136	3^	INV	Fractional exhaled nitric oxide increased/ elevated exhaled nitric oxide level	2	02OCT2020	22/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1152 11521233	3^	INFEC	Localised infection/ infection left index finger	2	01OCT2020	17/13	2	No	O	NA/TC	R (13OCT2020)	N/N
>55/ C459100 1 1152 11521260	3^	NEOPL	Malignant melanoma/ melanoma left shoulder	1	04SEP2020	5/35	3	No	O	NA/TC/TCN	R (08OCT2020)	Y/N
>55/ C459100	3^	MUSC	Muscle spasms/ back muscle spasms	1	04SEP2020	1/2	3	No	O	P	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1152 11521359		GENRL	Injection site induration/ injection site induration	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
			Injection site pain/ injection site tenderness	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
		NERV	Dysgeusia/ sour taste	1	06SEP2020	3/5	2	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1152 11521386	3^	SKIN	Rash/ rash on legs	1	22SEP2020	15/7	2	No	O	NA/TC	R (28SEP2020)	N/N
>55/ C459100 1 1152 11521417	3^	INFEC	Herpes zoster/ shingles	1	15SEP2020	7/20	2	Yes		NA/TC	R (04OCT2020)	N/N
>55/ C459100 1 1152 11521471	3^	GENRL	Injection site swelling/ Injection Site Reaction (swelling)	1	24SEP2020	1/1	1	Yes		NA/TCN	R (24SEP2020)	N/Y
>55/ C459100 1 1152 11521476	3^	EAR	Deafness unilateral/ hearing loss right ear	1	14OCT2020	20/10	3	Yes		P	R (23OCT2020)	N/N
>55/ C459100 1 1152 11521497	3^	NERV	Syncope/ vasovagal syncope	1	26OCT2020	20/	3	No	O	P/TC/TCN	UNK	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11156 11561001	3^	RESP	Oropharyngeal pain/ SORE THROAT	1	23AUG2020	5/8	1	No	O	NA	R (30AUG2020)	N/N
		INJ&P	Facial bones fracture/ FRACTURE OF ROOF OF RIGHT ORBITAL (GRADE 3)	2	06OCT2020	29/C	3	No	O	NA/TC	N	Y/N
			Fall/ FALL FROM BICYCLE	2	06OCT2020	29/1	2	No	O	NA	R (06OCT2020)	N/N
			Muscle strain/ PARTIAL TEAR OF THE RIGHT TRAPEZIUS MUSCLE (GRADE 1)	2	06OCT2020	29/C	2	No	O	NA/TC	RG	N/N
			Traumatic intracranial haemorrhage/ TRAUMATIC INTRACRANIAL HEMORRHAGE	2	06OCT2020	29/C	3	No	O	NA/TC	RG	Y/N
		MUSC	Arthropathy/ WIDENING OF ACROMIOCLAVICULAR JOINT SPACE (GRADE 1)	2	06OCT2020	29/C	2	No	O	NA/TC	RG	N/N
		NERV	Subarachnoid haemorrhage/ SUBARACHNOID HEMORRHAGE	2	06OCT2020	29/12	4	No	O	NA/TC	R (17OCT2020)	Y/N
>55/ C459100 11156 11561020	3^	GASTR	Diarrhoea/ diarrhea	2	16SEP2020	3/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ fatigue	2	16SEP2020	3/5	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 11156 11561025	3^	MUSC	Arthralgia/ arthralgia	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 11156 11561037	3^	MUSC	Myalgia/ muscle soreness	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C459100 11156 11561084	3^	MUSC	Myalgia/ myalgia	2	21SEP2020	1/5	1	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C459100 11156 11561095	3^	GENRL	Chills/ CHILLS	2	29SEP2020	7/2	1	Yes		NA	R (30SEP2020)	N/N
		NERV	Hypoaesthesia/ NUMBNESS OF LEFT UPPER EXTREMITY	2	23OCT2020	31/C	1	No	O	NA	RG	N/N
			Paraesthesia/ TINGLING OF LEFT UPPER EXTREMITY	2	23OCT2020	31/C	1	No	O	NA	RG	N/N
>55/ C459100 11156 11561099	3^	INFEC	Rash pustular/ bilateral papulopustular lesion on face	2	20OCT2020	26/1	1	No	O	NA/TC	R (20OCT2020)	N/N
>55/ C459100	3^	INFEC	Onychomycosis/ ONYCHOMYCOSIS	2	25SEP2020	1/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1156 11561100		MUSC	Back pain/ LUMBAGO	2	30SEP2020	6/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1156 11561114	3^	MUSC	Arthritis reactive/ REACTIVE ARTHRITIS	2	29SEP2020	2/8	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1156 11561127	3^	GENRL	Pyrexia/ fever	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1156 11561144	3^	EAR	Vertigo positional/ BENIGN PAROXYSMAL POSITIONAL VERTIGO	2	12OCT2020	6/4	1	No	O	NA/TC	R (15OCT2020)	N/N
>55/ C459100 1 1156 11561151	3^	GASTR	Diarrhoea/ diarrhea	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1156 11561152	3^	GASTR	Diarrhoea/ diarrhea	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100	3^	INJ&P	Muscle injury/ Left Hamstring Injury	1	29AUG2020	18/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1157 11571007 >55/ C459100	3^	RESP	Cough/ Cough	2	18SEP2020	15/1	1	No	O	NA	R (18SEP2020)	N/N
1 1157 11571008 >55/ C459100	3^	GENRL	Injection site pain/ Pain at injection site	2	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N
1 1157 11571014 >55/ C459100	3^	INFEC	Bronchitis/ Bronchitis	2	06OCT2020	33/20	3	No	O	NA/TC	R (25OCT2020)	N/N
1 1157 11571024 >55/ C459100	3^	GENRL	Injection site pain/ Injection Site Pain	1	15SEP2020	21/6	2	Yes		NA	R (20SEP2020)	N/N
1 1157 11571096		MUSC	Myalgia/ Left Biceps Pain	1	15SEP2020	21/6	2	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1157 11571116	3^	INFEC	Conjunctivitis/ Bilateral Conjunctivitis	2	28SEP2020	6/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1157 11571128	3^	MUSC	Myalgia/ General Muscle Aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11157 11571134	3^	NERV	Tremor/ Tremor	2	13OCT2020	20/C	2	No	CD	NA	N	N/N
		NERV	Transient ischaemic attack/ Suspected Transient Ischemic Attack	2	27OCT2020	34/2	3	No	O	NA/TC	R (28OCT2020)	Y/N
>55/ C459100 11157 11571139	3^	REPRO	Erectile dysfunction/ Erectile Dysfunction	1	04SEP2020	3/C	1	Yes		NA	N	N/N
>55/ C459100 11161 11611029	3^	INV	SARS-CoV-2 test positive/ SARS-COV-2 Positive	2	10NOV2020	7/C	3	No	O	NA	N	Y/N
		INFEC	Pneumonia/ pneumonia	2	11NOV2020	8/C	3	No	O	NA	N	Y/N
>55/ C459100 11161 11611038	3^	INJ&P	Fall/ Fell off step	1	15OCT2020	72/1	1	No	O	NA	R (15OCT2020)	N/N
			Humerus fracture/ Lt Shoulder fracture of humeral head	1	15OCT2020	72/C	2	No	O	NA/TC	N	N/N
>55/ C459100 11161 11611042	3^	NERV	Carpal tunnel syndrome/ worsening of carpal tunnel syndrome in lt hand	1	15OCT2020	71/C	1	No	O	NA/TC/TCN	RG	N/N
>55/ C459100	3^	RESP	Oropharyngeal pain/ sore throat*		03AUG2020	-3/2	1	No	CND	NA	R (04AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11162 11621014 >55/ C459100	3^	GENRL	Injection site pain/ Arm soreness (injection site pain)	2	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
11162 11621052 >55/ C459100	3^	INFEC	Pneumonia/ pneumonia	2	03SEP2020	2/11	3	No	O	NA/TC	RS (13SEP2020)	Y/N
11162 11621059 >55/ C459100	3^	GENRL	Fatigue/ Moderate Fatigue	2	02SEP2020	2/9	1	No	O	NA/TC	R (10SEP2020)	N/N
11162 11621071 >55/ C459100	3^	MUSC	Myalgia/ muscle aches	1	19AUG2020	2/3	1	Yes		NA	R (21AUG2020)	N/N
11162 11621149 >55/ C459100	3^	MUSC	Back pain/ Back Pain	1	28AUG2020	11/3	1	No	O	NA	R (30AUG2020)	N/N
11162 11621160 >55/ C459100	3^	GASTR	Diarrhoea/ Loose stools	1	29AUG2020	12/2	1	No	O	NA	R (30AUG2020)	N/N
11162 11621194 >55/ C459100	3^	MUSC	Neck pain/ Neck pain	1	26SEP2020	33/2	2	No	O	NA/TC	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GASTR	Diarrhoea/ Diarrhea	1	27SEP2020	34/2	1	No	O	NA	R (28SEP2020)	N/N
>55/ C459100 11162 11621196	3^	MUSC	Arthralgia/ R Hip Pain	2	08NOV2020	54/2	1	No	O	NA	R (09NOV2020)	N/N
>55/ C459100 11162 11621277	3^	GENRL	Pyrexia/ Fever	1	24SEP2020	22/2	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		UNC	CHILLS@@/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 11162 11621288	3^	RESP	Cough/ Cough	2	02OCT2020	5/2	1	No	O	NA	R (03OCT2020)	N/N
>55/ C459100 11162 11621312	3^	INFEC	Cellulitis/ Left leg Cellulitis	1	19SEP2020	12/C	2	No	O	NA/TC/TCN	RG	N/N
>55/ C459100 11162 11621327	3^	VASC	Arteriosclerosis/ Atherosclerotic Disease	1	13SEP2020	4/1	4	No	O	NA/W	F (13SEP2020)	Y/N
>55/ C459100 11162 11621359	3^	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11163 11631070	3^	GENRL	Injection site pain/ Left arm pain to injection site	2	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/Y
>55/ C459100 11163 11631099	3^	GENRL	Injection site pain/ LOCAL INJECTION SITE SORENESS (LEFT) DELTOID	2	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		NERV	Dizziness/ DIZZINESS	2	01SEP2020	2/2	1	No	O	NA	R (02SEP2020)	N/N
>55/ C459100 11167 11671015	3^	INFEC	Urinary tract infection/ Urinary Tract Infection	2	27OCT2020	48/C	1	No	O	NA/TC	N	N/N
>55/ C459100 11167 11671085	3^	CARD	Angina unstable/ Unstable Angina Pectoris	2	20OCT2020	34/1	2	No	O	NA/TC/TCN	R (20OCT2020)	Y/N
>55/ C459100 11167 11671137	3^	GENRL	Injection site erythema/ redness at injection site	2	26SEP2020	3/8	1	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100 11168 11681131	3^	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	1/4	2	Yes		NA	R (06SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
>55/ C459100	3^	GENRL	Chills/ chills	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11168 11681139			Fatigue/ fatigue	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
			Pyrexia/ low grade fever	2	26SEP2020	2/3	2	Yes		NA	R (28SEP2020)	N/N
		MUSC	Myalgia/ myalgia	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
>55/ C459100 11168 11681150	3^	MUSC	Arthralgia/ JOINT PAIN	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 11168 11681173	3^	MUSC	Myalgia/ myalgia	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
>55/ C459100 11168 11681205	3^	NERV	Headache/ headache	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C459100 11169 11691005	3^	MUSC	Pain in extremity/ Soreness Left Arm	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Sore Injection Site	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11169 11691006	3^	GENRL	Injection site pain/ Soreness at Injection Site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at Injection Site	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 11169 11691008	3^	GENRL	Fatigue/ Fatigue	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
			Injection site pain/ Pain at injection site	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N
			Injection site pruritus/ Itching at injection site	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
			Injection site swelling/ swelling at injection site	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
			Injection site pruritus/ Itching at injection site	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
			Injection site swelling/ Swelling at injection site	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
>55/ C459100 11169 11691013	3^	RESP	Cough/ Dry Cough	1	05SEP2020	2/2	1	No	O	NA	R (06SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Rhinorrhoea/ Rhinorrhea	1	05SEP2020	2/2	1	No	O	NA	R (06SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site pain	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
			Pain/ Generalized Body Aches	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C459100 11169 11691016	3^	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N
		GENRL	Injection site pain/ Pain at Injection Site	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C459100 11169 11691028	3^	GENRL	Injection site pain/ Injection Site Soreness	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/Y
		RESP	Bronchospasm/ Exercise Induced Bronchospasm	2	10NOV2020	42/1	1	No	O	NA	R (10NOV2020)	N/N
>55/ C459100 11169 11691032	3^	GENRL	Injection site pain/ Pain at injection site	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Mild Pain at Injection Site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 11169 11691035	3^	MUSC	Myalgia/ Entire body muscle pain	1	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11169 11691037	3^	MUSC	Myalgia/ Entire body muscle pain	2	03OCT2020	2/3	2	Yes		NA/TC	R (05OCT2020)	N/N
		MUSC	Pain in extremity/ Pain in left arm	1	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		GENRL	Pain/ Generalized Body Aches	1	24SEP2020	14/3	1	No	O	NA/TC	R (26SEP2020)	N/N
		GENRL	Chills/ chills	1	26SEP2020	16/2	1	No	O	NA/TC	R (27SEP2020)	N/N
		MUSC	Myalgia/ generalized muscle aches	1	26SEP2020	16/2	1	No	O	NA/TC	R (27SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	01OCT2020	1/2	1	No	O	NA	R (02OCT2020)	N/N
			Injection site pain/ Arm Soreness at Injection Site	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100 11169 11691042	3^	NERV	Headache/ Headache	2	01OCT2020	1/1	1	No	O	NA/TC	R (01OCT2020)	N/N
		MUSC	Arthralgia/ Painfull Right Shoulder	2	22OCT2020	18/6	2	No	O	NA/TC	R (27OCT2020)	N/N
			Neck pain/ Painfull Neck	2	22OCT2020	18/6	2	No	O	NA/TC	R (27OCT2020)	N/N
>55/ C459100	3^	NERV	Headache/ Headache	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1169 11691050		GENRL	Injection site pain/ Mild injection Site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1169 11691051	3^	GENRL	Injection site pain/ Pain at injection site	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ Tenderness at injection site	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1169 11691052	3^	NERV	Sinus headache/ Right Sided Sinus Headache	1	04OCT2020	19/8	1	No	O	NA/TC	R (11OCT2020)	N/N
>55/ C459100 1 1169 11691061	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ Mild pain at injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
>55/ C459100 1 1169 11691068	3^	GENRL	Injection site pain/ injection site pain	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
		MUSC	Joint range of motion decreased/ mild range of motion deficit left arm	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
		GASTR	Constipation/ worsening constipation	2	16OCT2020	8/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11169 11691070	3 [^]	MUSC	Pain in extremity/ Pain in left arm	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	19SEP2020	2/2	1	No	O	NA/TC	R (20SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
		MUSC	Arthralgia/ Entire Body Joint Aches	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 11169 11691071	3 [^]	GENRL	Chills/ Chills Post Shingrix Vaccine	2	13NOV2020	38/1	2	No	O	NA/TC	R (13NOV2020)	N/N
>55/ C459100 11169 11691074	3 ^{^†}	EYE	Retinal haemorrhage/ Left Eye Retinal hemorrhage	1	03OCT2020	2/C	2	No	O	NA	N	N/N
			Vitreous detachment/ Bilateral Vitreous Detachment	1	03OCT2020	2/C	2	No	O	NA	N	N/N
>55/ C459100 11170 11701004	3 [^]	GASTR	Diarrhoea/ Diarrhea	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
		GENRL	Chills/ Chills	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
			Injection site erythema/ Injection Site Redness	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1170 11701030	3 [^]	GENRL	Injection site pain/ Pain at injection site	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N	
			Injection site swelling/ Injection Site Swelling	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N	
			Pyrexia/ Fever	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N	
			MUSC	Arthralgia/ Joint Pain	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
			Myalgia/ Muscle Pain	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N	
			NERV	Headache/ Headache	2	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
			Chills/ Chills	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N	
>55/ C459100 1 1170 11701032	3 [^]	GENRL	Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N	
>55/ C459100 1 1170 11701032	3 [^]	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N	
>55/ C459100 1 1170 11701039	3 [^]	GENRL	Injection site pain/ Injection Site Pain	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N	
		GENRL	Chills/ Chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Injection site pain/ Injection Site Pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ Muscle Pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
>55/ C459100 11170 11701046	3^	GENRL	Injection site pain/ Pain at Injection Site	2	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
>55/ C459100 11170 11701050	3^	GENRL	Injection site pain/ Injection Site Pain	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 11170 11701053	3^	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Myalgia/ Muscle Pain Generalized	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 11170 11701058	3^	GASTR	Constipation/ Constipation	2	14SEP2020	4/3	2	No	O	NA/TC	R (16SEP2020)	N/N
		MUSC	Arthralgia/ Worsening Joint Pain	2	14SEP2020	4/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11170 11701062	3^	GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
		NERV	Headache/ Headache	1	25AUG2020	2/21	1	Yes		NA/TC	R (14SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	2/3	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C459100 11170 11701066	3^	SKIN	Rash/ General Body Rash	2	19SEP2020	6/8	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C459100 11170 11701067	3^	GENRL	Chills/ Chills	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Fatigue/ Fatigue	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 11170 11701068	3^	NERV	Headache/ Headache	1	26AUG2020	3/1	1	Yes		NA	R (26AUG2020)	N/N
>55/ C459100 11170 11701078	3^	GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1170 11701083	3^	GENRL	Fatigue/ Fatigue	1	27AUG2020	2/21	1	Yes		NA	R (16SEP2020)	N/N
		MUSC	Arthralgia/ Joint Pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1170 11701090	3^	GENRL	Fatigue/ Fatigue	2	23SEP2020	8/2	1	Yes		NA	R (24SEP2020)	N/N
			Malaise/ Malaise	2	23SEP2020	8/2	1	Yes		NA	R (24SEP2020)	N/N
		EYE	Vision blurred/ Blurred Vision	2	01OCT2020	16/31	2	No	O	NA	R (31OCT2020)	N/N
		GENRL	Asthenia/ General Weakness	2	01OCT2020	16/31	2	No	O	NA	R (31OCT2020)	N/N
		NERV	Dizziness/ Dizziness	2	01OCT2020	16/31	2	No	O	NA	R (31OCT2020)	N/N
>55/ C459100 1 1170 11701109	3^	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Injection site erythema/ Redness at Injection Site	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11170 11701114	3^	MUSC	Injection site pain/ Injection Site Pain	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Injection site swelling/ Swelling at Injection Site	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Myalgia/ Muscle Pain	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Soreness	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Injection site pain/ Injection Site Soreness	2	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	22SEP2020	5/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 11170 11701124	3^	NERV	Headache/ Headache	2	23SEP2020	6/3	2	Yes		NA/TC	R (25SEP2020)	N/N
		GENRL	Injection site pain/ Pain at Injection Site	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
			Injection site swelling/ Injection Site Swelling	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 11170 11701132	3^	NERV	Tremor/ Shakiness	1	07SEP2020	8/1	1	Yes		NA	R (07SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1170 11701133		GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1170 11701140	3^	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		MUSC	Arthralgia/ Joint Pain	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1170 11701141	3^	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
>55/ C459100 1 1170 11701147	3^	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Arthralgia/ Generalized Joint Pain	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11170 11701155	3^	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
			Injection site pain/ Injection site pain	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
			Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Pyrexia/ Fever	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
			Myalgia/ Generalized Muscle Pain	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N		
>55/ C459100 11170 11701157	3^	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 11170 11701160	3^	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11170 11701161	3^	MUSC	Myalgia/ General Muscle Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ General Muscle Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 11170 11701169	3^	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
>55/ C459100 11170 11701172	3^	GENRL	Chills/ Chills	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
			Injection site pain/ Injection Site Pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		MUSC	Myalgia/ General Muscle Pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11170 11701177	3^	MUSC	Myalgia/ Generalized Muscle Pain	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Cyst/ Cyst on Left Pinky	2	09OCT2020	17/C	1	No	O	NA	N	N/N
		GENRL	Fatigue/ Fatigue	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
>55/ C459100 11170 11701186	3^	NERV	Headache/ Headache	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Chills/ Chills	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Malaise/ Malaise	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Arthralgia/ Joint Pain	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
NERV	GENRL	Myalgia/ Myalgias	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N	
	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11170 11701188	3^	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 11170 11701194	3^	GENRL	Fatigue/ Fatigue	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		MUSC	Arthralgia/ Generalized Joint Pain	1	04SEP2020	2/3	1	Yes		NA/TC	R (06SEP2020)	N/N
			Myalgia/ General Muscle Pain	1	04SEP2020	2/3	1	Yes		NA/TC	R (06SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 11170 11701197	3^	GASTR	Nausea/ Queeziness	1	03SEP2020	1/7	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	05SEP2020	3/5	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 11170 11701198	3^	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/7	2	Yes		NA	R (09SEP2020)	N/N
			Injection site swelling/ Injection Site Swelling	1	03SEP2020	1/7	2	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GASTR	Nausea/ Queeziness	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
			Injection site erythema/ Injection Site Redness	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
			Injection site pain/ Injection Site Pain	2	24SEP2020	1/17	1	Yes		NA	R (10OCT2020)	N/N
			Injection site swelling/ Injection Site Swelling	2	24SEP2020	1/5	1	Yes		NA	R (28SEP2020)	N/N
>55/ C459100 1 1170 11701200	3^	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		NERV	Headache/ Headache	1	06SEP2020	4/1	1	Yes		NA	R (06SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	1/15	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1170 11701202	3^	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/1	1	Yes		NA	R (03SEP2020)	N/N
>55/ C459100 1 1170 11701217	3^	INJ&P	Limb injury/ Wound of left lower leg	1	12SEP2020	5/19	3	No	O	NA/TC	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		BLOOD	Neutropenia/ Neutropenia	2	01OCT2020	3/C	3	No	O	NA/TC/TCN	RG	Y/N
			Thrombocytopenia/ Thrombocytopenia	2	01OCT2020	3/C	2	No	O	NA	RG	Y/N
		INFECTION	Cellulitis/ Cellulitis of left lower leg	2	01OCT2020	3/C	3	No	O	NA/TC/TCN	RG	Y/N
>55/ C459100 11170 11701218	3^	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
>55/ C459100 11170 11701219	3^	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 11170 11701238	3^	GENRL	Injection site pain/ Pain at injection site	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Pyrexia/ Fever	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Pain at Injection Site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 11170 11701240	3^	GENRL	Chills/ Chills	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Headache	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11170 11701242	3^	GENRL	Chills/ Chills	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ Pain at Injection Site	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
		NERV	Headache/ Headache	1	22SEP2020	14/4	1	Yes		NA/TC	R (25SEP2020)	N/N
		GENRL	Injection site erythema/ Injection Site Redness	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
			Injection site pain/ Injection Site Soreness	2	28SEP2020	1/3	2	Yes		NA/TC	R (30SEP2020)	N/N
			Injection site pain/ Pain at Injection Site	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
			Injection site swelling/ Injection Site Swelling	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Malaise/ Malaise	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
	Pyrexia/ Fever	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N		
	NERV	Headache/ Headache	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N	
>55/ C459100	3^	GENRL	Chills/ Chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1170 11701246			Injection site pain/ Injection Site Tenderness	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
		NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1170 11701254	3^	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ Injection Site Pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		MUSC	Arthralgia/ Joint Pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Myalgia/ Muscle Pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ Headache	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1170 11701266	3^	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Injection site erythema/ Injection Site Redness	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11170 11701267	3^	GENRL	Injection site pain/ Pain at injection site	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
			Fatigue/ Fatigue	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Arthralgia/ Joint Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		EAR	Vertigo/ Vertigo	2	14OCT2020	15/15	1	No	O	NA	R (28OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		MUSC	Arthralgia/ Joint Ache	1	12SEP2020	3/3	1	Yes		NA/TC	R (14SEP2020)	N/N
		GENRL	Myalgia/ Myalgias	1	12SEP2020	3/3	1	Yes		NA/TC	R (14SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 11170 11701275	3^	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1170 11701277												
>55/ C459100 1 1170 11701278	3^	GENRL	Injection site pain/ Injection Site Pain	2	01OCT2020	1/5	1	Yes		NA/TC	R (05OCT2020)	N/N
		GENRL	Chills/ Chills	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
			Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
			Malaise/ Malaise	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
			Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100 1 1170 11701294	3^	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
			Pyrexia/ Fever	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		NERV	Headache/ Headache	2	02OCT2020	1/C	1	Yes		NA	N	N/N
>55/ C459100 1 1170 11701295	3^	GENRL	Injection site pain/ Injection Site Pain	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ Fatigue	2	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	02OCT2020	1/C	1	Yes		NA	RG	N/N
		GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
			Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 11170 11701309	3^	GENRL	Injection site pain/ Injection Site Pain	1	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
		NERV	Headache/ Intermittent Headache	1	14SEP2020	4/8	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 11170 11701327	3^	GENRL	Injection site pain/ Injection Site Pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 11170 11701329	3^	GENRL	Injection site erythema/ Injection Site Redness	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ Pain at Injection Site	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
			Injection site swelling/ Injection Site Swelling	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Generalized Muscle Pain	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1170 11701330	3 [†]	INFE	Conjunctivitis/ Conjunctivitis	1	06OCT2020	21/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1170 11701333	3 [^]	GENRL	Injection site pain/ Injection Site Pain	1	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	19SEP2020	4/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1170 11701335	3 [^]	GENRL	Injection site pain/ Injection Site Pain	1	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	23SEP2020	8/3	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1170 11701336	3 [^]	GENRL	Injection site pain/ Pain at injection Site	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1170 11701356	3 [^]	GENRL	Injection site pain/ Injection Site Pain	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
>55/ C459100 1 1170 11701368	3 [^]	GENRL	Injection site pain/ Injection Site Pain	1	22SEP2020	1/6	1	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11170 11701371	3^	GENRL	Fatigue/ Fatigue	1	24SEP2020	3/6	1	Yes		NA	R (29SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
		MUSC	Myalgia/ Muscle Pain	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
		NERV	Headache/ Headache	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 11171 11711007	3^	GENRL	Fatigue/ Fatigue	2	05SEP2020	6/3	2	Yes		NA	R (07SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	06SEP2020	7/2	2	Yes		NA	R (07SEP2020)	N/N
		NERV	Headache/ Headache	2	06SEP2020	7/2	1	Yes		NA	R (07SEP2020)	N/N
>55/ C459100 11171 11711015	3^	GENRL	Chills/ Chills	1	13AUG2020	1/2	1	Yes		NA	R (14AUG2020)	N/N
>55/ C459100 11171 11711040	3^	GENRL	Injection site pain/ Injection Site Pain [Left Arm Deltoid]	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11171 11711049	3^	INJ&P	Fall/ Fall	2	25SEP2020	18/1	2	No	O	NA	R (25SEP2020)	N/N
			Fibula fracture/ Fibula Fracture [Right]	2	25SEP2020	18/C	2	No	O	NA/TC	N	N/N
>55/ C459100 11171 11711064	3^	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 11171 11711102	3^	RESP	Oropharyngeal pain/ Sore Throat	2	26SEP2020	13/3	2	No	O	NA/TC	R (28SEP2020)	N/N
>55/ C459100 11171 11711107	3^	GENRL	Injection site pain/ Soreness around injection site	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
			Pain/ Body aches (generalized)	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
		NERV	Headache/ Headache	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 11171 11711180	3^	GENRL	Pyrexia/ Low grade fever	2	23SEP2020	1/3	1	Yes		NA/TC	R (25SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	23SEP2020	1/3	1	Yes		NA/TC	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11171 11711188	3^	GENRL	Fatigue/ Fatigue	1	04SEP2020	3/3	1	Yes		NA	R (06SEP2020)	N/N
			Injection site pain/ Left Arm pain (At the injection site)	1	04SEP2020	3/3	1	Yes		NA	R (06SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	1	04SEP2020	3/3	1	Yes		NA	R (06SEP2020)	N/N
>55/ C459100 11171 11711199	3^	RESP	Cough/ Worsening of Cough	2	18OCT2020	19/13	2	No	O	NA	R (30OCT2020)	N/N
>55/ C459100 11171 11711201	3^	MUSC	Pain in extremity/ Arm Pain [Left]	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		NERV	Headache/ Headache	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		METAB	Hyperlipidaemia/ Worsening of hyperlipidemia	2	21OCT2020	22/C	1	No	O	NA/TC	N	N/N
			Type 2 diabetes mellitus/ Worsening of diabetes type II	2	21OCT2020	22/C	1	No	O	NA/TC	N	N/N
>55/ C459100 11171 11711208	3^	GENRL	Injection site pain/ Injection site soreness	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1171 11711217 >55/ C459100 1 1171 11711220	3^	GASTR	Nausea/ Nausea	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1171 11711227	3^	GASTR	Diarrhoea/ Diarrhea	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site pain/ Arm pain (at the injection site)	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1171 11711233	3^	INV	Blood glucose fluctuation/ Worsening Blood Sugar Fluctuation	2	28SEP2020	1/C	1	No	O	NA	N	N/N
>55/ C459100 1 1171 11711243	3^	MUSC	Pain in extremity/ Pain in Arm [Left]	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
>55/ C459100 1 1171 11711276	3^	GENRL	Injection site pain/ Left Arm Pain (at the inject site)	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
>55/ C459100	3^	MUSC	Myalgia/ Muscle aches, generalized	1	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1171 11711302		MUSC	Myalgia/ Muscle aches, generalized	2	27OCT2020	2/2	2	Yes		NA/TC	R (28OCT2020)	N/N
>55/ C459100 1 1174 11741022	3^	EAR	Tinnitus/ Bilateral Tinnitus	1	13SEP2020	11/C	1	No	O	NA	N	N/N
>55/ C459100 1 1174 11741042	3^	RENAL	Hydronephrosis/ Hydronephrosis	1	02OCT2020	17/5	2	No	O	NA/TC/TCN	R (06OCT2020)	N/N
			Nephrolithiasis/ nephrolithiasis	1	02OCT2020	17/5	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N
>55/ C459100 1 1174 11741069	3^	SKIN	Rash/ Rash left upper arm	1	22SEP2020	1/4	1	No	O	NA	R (25SEP2020)	N/N
>55/ C459100 1 1177 11771006	3^	RESP	Oropharyngeal pain/ SORE THROAT, MILD INTERMITTENT	1	14AUG2020	3/11	1	No	O	NA	R (24AUG2020)	N/N
>55/ C459100 1 1177 11771012	3^	RESP	Pulmonary embolism/ Right Lower Lobe Pulmonary Artery Embolus	2	01OCT2020	29/C	2	No	O	NA/TC	N	N/N
		VASC	Aortic aneurysm/ Aortic Aneurysm	2	01OCT2020	29/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11177 11771055	3^	EAR	Tinnitus/ TINNITUS	2	08SEP2020	1/4	1	No	O	NA	R (11SEP2020)	N/N
		GENRL	Injection site pain/ MUSCLE PAIN AT INJECTION SITE	2	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 11177 11771063	3^	NEOPL	Malignant melanoma/ MELANOMA	2	29SEP2020	22/C	2	No	O	NA	N	N/N
>55/ C459100 11177 11771069	3^	MUSC	Myalgia/ MUSCLE PAIN, BOTH ARMS	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 11177 11771089	3^	GENRL	Injection site pain/ Injection Site Pain	2	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 11177 11771115	3^	GENRL	Injection site pain/ Injection Site Pain	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		GENRL	Chills/ Chills	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 11177 11771143	3^	GENRL	Pyrexia/ FEVER	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11177 11771178	3^	INJ&P	Fall/ MECHANICAL FALL	1	03SEP2020	8/1	3	No	O	NA	R (03SEP2020)	N/N
			Spinal compression fracture/ LUMBAR COMPRESSION FRACTURE, L1	1	03SEP2020	8/C	2	No	O	NA/TC	N	N/N
>55/ C459100 11177 11771299	3^	GENRL	Pyrexia/ Fever	1	05SEP2020	1/2	2	Yes		NA	R (06SEP2020)	N/N
>55/ C459100 11177 11771353	3^	MUSC	Pain in extremity/ Pain, Left toe	1	14SEP2020	1/3	2	No	O	NA	R (16SEP2020)	N/N
>55/ C459100 11177 11771370	3^	GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 11177 11771380	3^	GASTR	Aphthous ulcer/ Aphthous Ulcers	1	19SEP2020	3/C	2	Yes		NA/TC	RG	N/N
		GENRL	Fatigue/ Fatigue	2	09OCT2020	2/10	1	Yes		NA	R (18OCT2020)	N/N
>55/ C459100 11177 11771421	3^	GENRL	Fatigue/ FATIGUE	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ HEADACHE	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 11177 11771431	3^	GENRL	Pain/ Generalized Body Aches	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 11177 11771448	3^	GASTR	Diarrhoea/ DIARRHEA	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Asthenia/ WEAKNESS	1	25SEP2020	1/1	2	Yes		NA	R (25SEP2020)	N/N
		SKIN	Cold sweat/ COLD SWEATS	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN, LEFT ARM	1	27SEP2020	3/3	1	Yes		NA	R (29SEP2020)	N/N
		GENRL	Pyrexia/ FEVER	1	28SEP2020	4/7	1	Yes		NA/TC	R (04OCT2020)	N/N
		NERV	Headache/ HEADACHE	1	28SEP2020	4/7	1	Yes		NA/TC	R (04OCT2020)	N/N
		GENRL	Injection site pain/ Injection Site Pain, Left Arm	2	16OCT2020	1/17	1	Yes		NA	R (01NOV2020)	N/N
>55/ C459100 11177 11771457	3^	GENRL	Injection site pain/ Injection Site Pain	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
>55/ C459100	3^	GENRL	Fatigue/ Fatigue	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1178 11781002			Injection site pain/ Injection site muscle soreness left arm	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
		INV	Body temperature increased/ increased temperature	1	22AUG2020	2/2	2	Yes		NA	R (23AUG2020)	N/N
>55/ C459100 1 1178 11781005	3^	EAR	Vertigo/ vertigo-intermittent	1	30AUG2020	7/24	2	Yes		NA/TCN	R (22SEP2020)	N/N
>55/ C459100 1 1178 11781006	3^	GENRL	Injection site pain/ injection site soreness	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Injection site erythema/ redness at injection site, left arm	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
			Injection site pain/ soreness at injection site, left arm	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
			Malaise/ malaise	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1178 11781007	3^	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/3	1	Yes		NA/TC	R (17SEP2020)	N/N
		MUSC	Myalgia/ Generalized myalgia	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11178 11781011	3^	GENRL	Fatigue/ intermittent fatigue	1	26AUG2020	3/7	1	Yes		NA	R (01SEP2020)	N/N
		RESP	Upper-airway cough syndrome/ post-nasal drip (intermittent)	1	27AUG2020	4/5	1	Yes		NA	R (31AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 11178 11781015	3^	GENRL	Injection site pain/ injection site tenderness	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		NERV	Transient global amnesia/ transient global amnesia	2	10OCT2020	26/1	3	No	O	NA	R (10OCT2020)	Y/N
		VASC	Aortic dilatation/ Ascending aorta ectasia	2	10OCT2020	26/C	1	No	O	NA	N	N/N
		CARD	Left ventricular dysfunction/ Diastolic dysfunction of the left ventricle	2	11OCT2020	27/C	1	No	O	NA	N	N/N
>55/ C459100 11178 11781017	3^	NERV	Headache/ headache	1	25AUG2020	1/2	1	Yes		NA/TC	R (26AUG2020)	N/N
		INFEC	Herpes zoster/ shingles outbreak	1	28AUG2020	4/8	1	Yes		NA	R (04SEP2020)	N/N
		NERV	Headache/ headache	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
>55/ C459100	3^	GENRL	Fatigue/ fatigue	1	26AUG2020	1/2	2	Yes		NA	R (27AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1178 11781021			Injection site pain/ injection site tenderness	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Injection site pain/ Injection site tenderness	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	17/1	1	No	O	NA	R (01OCT2020)	N/N
		CARD	Angina pectoris/ angina pectoris	2	20OCT2020	36/C	1	No	O	NA	N	N/N
>55/ C459100 1 1178 11781024	3^	GENRL	Injection site bruising/ bruising at injection site	2	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ tenderness at injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1178 11781025	3^	RENAL	Nephrolithiasis/ kidney stones	2	19SEP2020	4/5	3	No	O	NA/TC	R (23SEP2020)	Y/N
		INFEC	Pyelonephritis/ Pyelonephritis	2	03OCT2020	18/28	2	No	O	NA/TC	R (30OCT2020)	Y/N
		RENAL	Nephrolithiasis/ Kidney stone, worsening	2	03OCT2020	18/14	3	No	O	NA/TC	R (16OCT2020)	N/N
>55/ C459100	3^	GASTR	Toothache/ generalized teeth ache	1	27AUG2020	2/3	1	No	O	NA	R (29AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1178 11781027		GENRL	Pain/ generalized body ache	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		NERV	Headache/ headache	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
			Pain/ Generalized body ache	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1178 11781028	3^	GENRL	Injection site pain/ Left deltoid soreness at injection site	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1178 11781032	3^	GENRL	Injection site pain/ Tenderness at injection site	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1178 11781033	3^	INJ&P	Contusion/ Bruising - bilateral forearms	1	30AUG2020	4/C	1	No	O	NA	N	N/N
>55/ C459100	3^	INJ&P	Contusion/ bruising, bilateral upper extremities	1	03SEP2020	8/22	1	No	O	NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1178 11781035		GENRL	Injection site pain/ Injection site tenderness	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1178 11781039	3^	SKIN	Acne/ whiteheads, bilateral ears	1	11SEP2020	15/34	1	No	O	NA	R (14OCT2020)	N/N
		GENRL	Injection site discomfort/ discomfort at injection site	2	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
		MUSC	Arthralgia/ right shoulder pain	2	21OCT2020	36/3	1	No	O	NA/TC	R (23OCT2020)	N/N
>55/ C459100 1 1178 11781047	3^	PSYCH	Libido increased/ Increased Libido	1	10SEP2020	11/29	1	No	O	NA	R (08OCT2020)	N/N
>55/ C459100 1 1178 11781048	3^	GASTR	Salivary gland calculus/ salivary gland stone	1	20SEP2020	21/C	2	No	O	NA/TC	RG	Y/N
>55/ C459100 1 1178 11781057	3^	GASTR	Diarrhoea/ diarrhea	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
		GENRL	Injection site pain/ injection site tenderness, left arm	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ chills	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)			
		GENRL	Chills/ chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N			
			Fatigue/ fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N			
			Pain/ generalized body ache	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N			
			Pyrexia/ Fever	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N			
>55/ C459100 11178 11781059	3^	GENRL	Injection site pain/ Injection Site Soreness	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N			
		GENRL	Chills/ Chills	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N			
			>55/ C459100 11178 11781064	3^	GENRL	Injection site pain/ Injection site soreness	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
						Injection site swelling/ Injection site swelling	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N			
			Injection site swelling/ Injection site swelling	2	22SEP2020	1/9	2	Yes		NA	R (30SEP2020)	N/N			
			Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N			
>55/ C459100	3^	GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N			

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1178 11781081		GENRL	Fatigue/ fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		SKIN	Night sweats/ night sweats	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1178 11781086	3^	NEOPL	Basal cell carcinoma/ Basal cell carcinoma (nose)	2	20OCT2020	28/C	2	No	O	NA	N	N/N
>55/ C459100 1 1178 11781093	3^	GASTR	Diarrhoea/ loose stools	1	08SEP2020	6/4	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1178 11781099	3^	GENRL	Injection site pain/ Soreness at injection site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Pain/ generalized body ache	2	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N
			Pyrexia/ fever	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1178 11781101	3^	MUSC	Osteoarthritis/ osteoarthritis	1	14SEP2020	11/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11178 11781103	3^	MUSC	Pain in extremity/ Left arm soreness	1	04SEP2020	1/4	2	Yes		NA	R (07SEP2020)	N/N
		SKIN	Urticaria/ Urticaria	1	05SEP2020	2/3	2	Yes		NA/TC	R (07SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		MUSC	Myalgia/ Generalized muscle ache	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 11178 11781108	3^	GENRL	Injection site pain/ injection site pain, left arm	1	05SEP2020	2/1	2	Yes		NA/TC	R (05SEP2020)	N/N
>55/ C459100 11178 11781109	3^	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 11178 11781122	3^	NEOPL	Basal cell carcinoma/ Basal Cell Carcinoma (face)	2	15OCT2020	18/C	2	No	O	NA	N	N/N
>55/ C459100 11178 11781123	3^	GASTR	Abdominal distension/ bloating, abdominal	1	23SEP2020	16/3	1	No	O	NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11178 11781125	3^	GENRL	Pyrexia/ fever	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		MUSC	Myalgia/ myalgias	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 11178 11781132	3^	INJ&P	Wrist fracture/ Fracture left wrist	2	09OCT2020	11/C	2	No	O	NA/TC/TCN	N	N/N
>55/ C459100 11178 11781134	3^	GENRL	Injection site pain/ pain at injection site	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 11178 11781136	3^	MUSC	Myalgia/ Diffuse myalgias	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
>55/ C459100 11178 11781138	3^	RENAL	Nocturia/ nocturia	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		CARD	Coronary artery disease/ vascular disease (coronary artery disease)	2	08OCT2020	10/C	3	No	O	NA/TC	N	N/N
			Myocardial infarction/ Myocardial infarction	2	08OCT2020	10/12	3	No	O	NA	R (19OCT2020)	Y/N
>55/ C459100	3^	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1178 11781140		INJ&P	Wrist fracture/ Left wrist fracture	2	15OCT2020	17/C	2	No	O	NA/TC/TCN	N	N/N
>55/ C459100 1 1178 11781143	3^	GENRL	Malaise/ malaise	1	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
		GENRL	Injection site pain/ Injection site soreness	2	01OCT2020	2/4	1	Yes		NA	R (04OCT2020)	N/N
			Malaise/ Malaise	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 1 1178 11781146	3^	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/5	2	Yes		NA	R (14SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
			Pyrexia/ fever	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		MUSC	Myalgia/ generalized muscle ache	1	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
		NERV	Headache/ headache	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Chills/ chills	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
			Pyrexia/ fever	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11178 11781147	3^	MUSC	Myalgia/ generalized muscle ache	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		NERV	Headache/ headache	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		RESP	Sneezing/ sneezing	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 11178 11781148	3^	VASC	Hypertension/ exacerbation of hypertension	1	28SEP2020	19/C	1	No	O	NA/TC	N	N/N
		GENRL	Injection site pain/ injection site pain	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
		GENRL	Injection site pain/ Tenderness at injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 11178 11781151	3^	NERV	Headache/ Headache	2	03OCT2020	2/1	2	Yes		NA	R (03OCT2020)	N/N
		GENRL	Injection site pain/ injection site tenderness	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
>55/ C459100 11178 11781157	3^	GENRL	Injection site pain/ Pain at injection site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100	3^	GENRL	Pyrexia/ Fever	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11178 11781158		GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ Pain at injection site	2	01OCT2020	2/5	1	Yes		NA	R (05OCT2020)	N/N
>55/ C459100 11178 11781160	3^	GENRL	Injection site pain/ tenderness at injection site	1	18SEP2020	8/5	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 11178 11781164	3^	BLOOD	Lymphadenopathy/ lymphadenopathy, rught axilla	2	14OCT2020	10/8	1	Yes		NA	R (21OCT2020)	N/N
>55/ C459100 11178 11781166	3^	MUSC	Arthralgia/ Left hip pain	2	20OCT2020	16/C	1	No	O	NA/TC	RG	N/N
		INJ&P	Skin laceration/ Laceration, Left lower leg	2	29OCT2020	25/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 11178 11781167	3^	HEPAT	Cholecystitis/ cholecystitis	2	09OCT2020	5/4	3	No	O	NA/TC/TCN	R (12OCT2020)	Y/N
			Cholelithiasis/ cholelithiasis (gallstones)	2	09OCT2020	5/3	3	No	O	NA/TC/TCN	R (11OCT2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Tenderness at injection site	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11178 11781173		GENRL	Chills/ chills	1	06OCT2020	22/2	1	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/ Tenderness at injection site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		GASTR	Abdominal pain/ intermittent Right abdominal pain	2	17OCT2020	12/C	1	No	O	NA	N	N/N
>55/ C459100 11178 11781176	3^	RENAL	Urine odour abnormal/ urine odor	1	19SEP2020	5/C	1	No	O	NA	N	N/N
>55/ C459100 11178 11781178	3^	GENRL	Injection site pain/ Tenderness at injection site	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Malaise/ generalized malaise	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
			Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C459100 11178 11781184	3^	GENRL	Injection site pain/ Pain at injection site	1	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
			Pain/ Body aches	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Soreness of injection site	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1178 11781195		GENRL	Injection site pain/ Tenderness at injection site	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1178 11781196	3^	GENRL	Fatigue/ Fatigue	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Injection site pain/ Soreness at injection site - Left arm	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
			Injection site pain/ soreness at injection site, left arm	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
>55/ C459100 1 1178 11781199	3^	GENRL	Fatigue/ Fatigue	2	07OCT2020	1/8	1	Yes		NA	R (14OCT2020)	N/N
		NERV	Headache/ Headache	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N
>55/ C459100 1 1178 11781205	3^	GENRL	Injection site pain/ injection site tenderness	1	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
		SKIN	Rash/ generalized upper body rash	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1178 11781212	3^	GENRL	Injection site pain/ tenderness at injection site	1	18SEP2020	1/6	1	Yes		NA	R (23SEP2020)	N/N
			Injection site swelling/ swelling, injection site	1	18SEP2020	1/6	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Intervertebral disc degeneration/ exacerbation of degenerative disc disease	2	28OCT2020	20/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1178 11781225	3^	GENRL	Injection site pain/ left deltoid soreness at site of injection	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
>55/ C459100 1 1178 11781229	3^	GENRL	Injection site pain/ injection site soreness	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1178 11781235	3^	GENRL	Injection site pain/ Pain at injection site.	1	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1178 11781241	3^	REPRO	Prostatomegaly/ Exacerbation of enlarged prostate	1	05OCT2020	13/C	2	No	O	NA	N	N/N
		GENRL	Injection site pain/ Injection site tenderness.	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11178 11781242	3^	VASC	Hypertension/ hypertension	1	09OCT2020	17/C	1	No	O	NA/TC	N	N/N
>55/ C459100 11178 11781252	3^	GENRL	Injection site pain/ tenderness at injection site	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 11178 11781255	3^	GENRL	Nodule/ Nodule/lump left arm below injection site.	1	12OCT2020	18/5	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 11178 11781256	3^	MUSC	Muscular weakness/ Decreased strength in both arms.	1	01OCT2020	7/15	1	No	O	NA	R (15OCT2020)	N/N
>55/ C459100 11178 11781259	3^	GASTR	Nausea/ nausea	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		GENRL	Chills/ chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 11178 11781261	3^	GENRL	Injection site pain/ Left deltoid soreness at site of injection.	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N
>55/ C459100	3^	GASTR	Diarrhoea/ Diarrhea	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11178 11781274		GENRL	Chills/ Chills	1	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Fatigue	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N
		REPRO	Pelvic pain/ pelvic pain	1	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		MUSC	Arthralgia/ joint pain	2	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
		NERV	Headache/ headache	2	23OCT2020	1/2	1	Yes		NA/TC	R (24OCT2020)	N/N
		GENRL	Chills/ chills	2	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N
>55/ C459100 11178 11781278	3^	GENRL	Injection site pain/ pain beyond injection site	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 11178 11781293	3^	GENRL	Injection site pain/ injection site soreness	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 11178 11781294	3^	MUSC	Myalgia/ Myalgias intermittent	1	09OCT2020	2/14	1	Yes		NA/TC	R (22OCT2020)	N/N
>55/ C459100	3^	INV	Body temperature increased/ Elevated temperature of 99.6 Fahrenheit.	1	10SEP2020	3/2	1	No	O	NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11179 11791062		SKIN	Rash/ Rash on bilateral hands and left lower extremity.	1	10SEP2020	3/2	1	No	O	NA/TC	RS (11SEP2020)	N/N
>55/ C459100 11204 12041003	3^	GENRL	Pyrexia/ mild fever	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 11204 12041007	3^	GENRL	Pyrexia/ fever, 101.1F	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		MUSC	Myalgia/ generalized muscle aches	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 11204 12041014	3^	GENRL	Fatigue/ Mild Fatigue	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 11204 12041032	3^	GENRL	Feeling hot/ feeling warm post vaccine #2 administration	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N
		MUSC	Pain in extremity/ left arm pain	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 11204 12041035	3^	NERV	Headache/ Headache	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1204 12041037	3^	MUSC	Pain in extremity/ arm tenderness moderate, no fevers	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
>55/ C459100 1 1204 12041042	3^	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/4	2	Yes		NA/TC	R (07SEP2020)	N/N
		NERV	Dizziness/ Dizziness	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/Y
		GENRL	Fatigue/ fatigue	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		MUSC	Pain in extremity/ right arm pain	2	26SEP2020	2/4	1	Yes		NA/TC	R (29SEP2020)	N/N
>55/ C459100 1 1204 12041054	3^	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
			Pyrexia/ Low grade fever, 101	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1204 12041068	3^	MUSC	Pain in extremity/ sore arm	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		METAB	Decreased appetite/ loss of appetite	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100	3^	MUSC	Pain in extremity/ left arm pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1204 12041069	3^	NERV	Headache/ Headache	1	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
1 1204 12041104		GENRL	Vaccination site pain/ left arm pain (vac#2 injection site)	2	06OCT2020	1/4	1	Yes		NA	R (09OCT2020)	N/N
		NERV	Headache/ headache	2	07OCT2020	2/4	1	Yes		NA/TC	R (10OCT2020)	N/N
>55/ C459100 1 1204 12041106	3^	GENRL	Vaccination site pain/ left arm soreness (vac #2 injection site)	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		GENRL	Pyrexia/ low grade fever, 100.0	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1204 12041115	3^	GASTR	Nausea/ Nausea	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Mild soreness at injection site	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1204 12041126	3^	GASTR	Diarrhoea/ non-bloody diarrhea	1	20SEP2020	3/5	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	23SEP2020	6/3	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1204 12041162	3 [†]	GENRL	Injection site pain/ left arm pain (injection site)	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Pyrexia/ Low grade fever 100.6 F	1	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1204 12041166	3 [^]	MUSC	Myalgia/ Generalized muscle aches	1	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
		NERV	Headache/ Headache	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1204 12041169	3 [^]	GENRL	Injection site pain/ Muscle tenderness at injection site	1	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
		NERV	Headache/ Headache	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 1 1204 12041212	3 [^]	GENRL	Chills/ Chills	2	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
			Pyrexia/ Low grade fever, 101.0	2	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
>55/ C459100 1 1219 12191005	3 [^]	SKIN	Dermatitis contact/ itchy maculopapular rash, anterior neck - suspected contact dermatitis	1	05OCT2020	4/21	1	No	O	NA	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1219 12191010	3^	GENRL	Fatigue/ fatigue	2	29OCT2020	3/1	1	Yes		NA	R (29OCT2020)	N/N
		NERV	Headache/ headache	2	29OCT2020	3/1	1	Yes		NA/TC	R (29OCT2020)	N/N
>55/ C459100 1 1219 12191011	3^	GENRL	Injection site pain/ injection site soreness only with movement of left arm	1	06OCT2020	1/C	1	Yes		NA	N	N/Y
>55/ C459100 1 1223 12231009	3^	SKIN	Rash erythematous/ Left shoulder erythematous rash	2	20SEP2020	4/2	1	Yes		NA	R (21SEP2020)	N/N
>55/ C459100 1 1223 12231011	3^	GENRL	Injection site pain/ Injection Site Soreness	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Chills/ Chills	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ Fever	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
		INV	Blood glucose increased/ Glucose Spike (350)	2	18SEP2020	2/5	3	Yes		NA	R (22SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1223 12231020	3^	MUSC	Pain in extremity/ Right arm soreness	2	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C459100 1 1223 12231029	3^	GENRL	Injection site pain/ soreness at injection site	1	29AUG2020	1/2	1	Yes		NA	R (30AUG2020)	N/N
>55/ C459100 1 1223 12231037	3^	SURG	Carpal tunnel decompression/ left ulner carpel tunnel surgery	2	29SEP2020	9/1	1	No	O	NA/TCN	R (29SEP2020)	N/N
>55/ C459100 1 1223 12231040	3^	MUSC	Limb discomfort/ arm discomfort	2	22SEP2020	2/4	1	Yes		NA/TC	R (25SEP2020)	N/N
			Neck pain/ neck pain	2	22SEP2020	2/12	2	Yes		NA/TC	R (03OCT2020)	N/N
		MUSC	Arthralgia/ joint pain	2	23SEP2020	3/4	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1223 12231049	3^	MUSC	Arthralgia/ joint pain	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		NERV	Dizziness/ lightheaded	2	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
			Headache/ headache	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1223 12231065	3^	MUSC	Myalgia/ Myalgia	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
			Pain in extremity/ Left arm pain	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
>55/ C459100 1 1223 12231091	3^	GENRL	Pyrexia/ fever	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
		MUSC	Pain in extremity/ sore left arm	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1223 12231097	3^	GASTR	Constipation/ intermittent constipation	2	28OCT2020	34/2	1	No	O	NA/TC	R (29OCT2020)	N/N
		GENRL	Asthenia/ Generalized Weakness	2	12NOV2020	49/C	3	No	O	NA/TC	N	Y/N
>55/ C459100 1 1223 12231123	3^	GENRL	Injection site pain/ injection site soreness	2	29SEP2020	1/4	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1223 12231136	3^	GENRL	Asthenia/ generalized weakness	2	01OCT2020	1/2	2	Yes		NA	R (02OCT2020)	N/N
			Chills/ chills	2	01OCT2020	1/2	2	Yes		NA	R (02OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ muscle aches	2	01OCT2020	1/2	2	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ headaches	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		INFEC	Oral herpes/ herpes lower lip lesion	2	28OCT2020	28/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1223 12231140	3^	GASTR	Diarrhoea/ diarrhea	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1223 12231142	3^	MUSC	Pain in extremity/ left arm soreness	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 1 1223 12231156	3^	MUSC	Pain in extremity/ left sore arm	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1223 12231159	3^	GASTR	Pancreatic mass/ Mass at Pancreatic Head	2	05NOV2020	36/C	3	No	O	NA/TC/TCN	N	Y/N
>55/ C459100 1 1223 12231182	3^	INFEC	Diverticulitis/ progression of diverticulitis	1	29SEP2020	14/C	3	No	O	NA/TC	RG	Y/N
		INFEC	Abscess intestinal/ Pericolonic Abscess	2	13OCT2020	5/C	4	No	O	NA/TC/TCN	N	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1223 12231193	3^	GENRL	Pyrexia/ fever	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
>55/ C459100 1 1223 12231227	3^	MUSC	Arthralgia/ left sided shoulder pain	1	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1224 12241004	3^	GASTR	Diarrhoea/ Diarrhea	2	25SEP2020	26/1	1	No	O	NA	R (25SEP2020)	N/N
>55/ C459100 1 1224 12241012	3^	INJ&P	Ankle fracture/ Lateral Malleolus Fracture - left ankle	1	19AUG2020	7/C	2	No	O	P/TC/TCN/W	N	N/N
			Fall/ FALL	1	19AUG2020	7/1	2	No	O	NA/W	RS (19AUG2020)	N/N
		MUSC	Muscular weakness/ Diffuse weakness in extremities (Bilateral legs and Left arm)	1	19AUG2020	7/7	2	No	O	NA/W	RS (25AUG2020)	N/N
		NERV	Transient ischaemic attack/ Suspected TIA	1	19AUG2020	7/1	2	No	O	NA/W	RS (19AUG2020)	N/N
>55/ C459100 1 1224 12241030	3^	VASC	Hypertension/ Worsening of Hypertension	1	02SEP2020	17/C	1	No	O	NA/TC	N	N/N
		GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1224 12241033	3^	METAB	Pain/ Body aches	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
			Pyrexia/ Fever (99.5)	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Decreased appetite/ Loss of Appetite	2	10SEP2020	2/11	1	Yes		NA	R (20SEP2020)	N/N	
		MUSC	Arthralgia/ Hip Pain - Right	2	14SEP2020	6/11	1	No	O	NA	R (24SEP2020)	N/N
>55/ C459100 1 1224 12241036	3^	GENRL	Drug withdrawal syndrome/ Diarrhea - Oxycontin Withdrawal	1	04SEP2020	18/7	1	No	O	NA	R (10SEP2020)	N/N
>55/ C459100 1 1224 12241039	3^	MUSC	Drug withdrawal syndrome/ Nausea - Oxycontin Withdrawal	1	04SEP2020	18/7	1	No	O	NA	R (10SEP2020)	N/N
			Myalgia/ Soreness - Left Deltoid	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		GASTR	Nausea/ Nausea	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		GENRL	Chills/ Chills	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		Pyrexia/ Fever - 99.5	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N	
INJ&P	Joint dislocation/ Right hip dislocation	2	06OCT2020	29/1	2	No	O	NA/TC/TCN	R (06OCT2020)	N/N		

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Osteoarthritis/ Chronic Degenerative Changes in Left Hip	2	06OCT2020	29/C	1	No	O	NA	N	N/N
			Osteoarthritis/ Chronic Degenerative Changes in Pubic Symphyses	2	06OCT2020	29/C	1	No	O	NA	N	N/N
			Spinal osteoarthritis/ Chronic Degenerative Changes in bilateral sacro iliac joints	2	06OCT2020	29/C	1	No	O	NA	N	N/N
>55/ C459100 1 1224 12241042	3^	GENRL	Injection site pruritus/ Pruritus around injection site	2	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1224 12241045	3^	GASTR	Abdominal pain upper/ Stomach Cramps	2	28SEP2020	20/3	1	No	O	NA	R (30SEP2020)	N/N
		GENRL	Pyrexia/ Low Grade Fever	2	29SEP2020	21/2	1	No	O	NA	R (30SEP2020)	N/N
>55/ C459100 1 1224 12241070	3^	MUSC	Arthralgia/ Hip Pain - right side	1	27AUG2020	4/C	1	No	O	NA	N	N/N
>55/ C459100 1 1224 12241082	3^	INJ&P	Ligament rupture/ Torn Anterior Cruciate Ligament - Left	2	28SEP2020	7/2	2	No	O	NA/TC/TCN	R (29SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1224 12241107	3^	INFEC	Herpes zoster/ Shingles	2	17OCT2020	27/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1224 12241112	3^	NERV	Dysgeusia/ Worsening of Copper Taste (in mouth)	2	21SEP2020	1/C	1	Yes		NA	N	N/N
		CARD	Atrial flutter/ Atrial Flutter	2	25SEP2020	5/1	2	No	O	NA	R (25SEP2020)	N/N
>55/ C459100 1 1224 12241122	3^	GENRL	Pyrexia/ Low Grade Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ Muscle Soreness	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		NERV	Lethargy/ Lethargy	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		NERV	Sinus headache/ Sinus Headache	2	24SEP2020	3/2	2	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1224 12241125	3^	GENRL	Pyrexia/ Fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Lethargy/ Lethargy	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100	3^	EYE	Vision blurred/ Blurry Vision	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11224 12241154		GENRL	Chills/ Cold Chills	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
			Pain/ Body Aches	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
			Pyrexia/ Fever	2	30SEP2020	2/2	3	Yes		NA/TC	R (01OCT2020)	N/N
		NERV	Lethargy/ Lethargy	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
		VASC	Flushing/ Flushed	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 11226 12261028	3^	NERV	Dizziness/ dizziness	2	01OCT2020	36/1	2	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C459100 11226 12261034	3^	VASC	Hypertension/ Worsening of systemic arterial hypertension	2	22OCT2020	57/C	3	No	O	NA/TC	RG	N/N
>55/ C459100 11226 12261062	3^	NERV	Headache/ Headache	1	17AUG2020	8/1	1	Yes		NA/TC	R (17AUG2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	10SEP2020	11/2	1	No	O	NA	R (11SEP2020)	N/N
>55/ C459100	3^	RESP	Oropharyngeal discomfort/ Throat discomfort	2	22OCT2020	53/3	1	No	O	NA/TC	R (24OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261077 >55/ C459100	3^	RESP	Rhinorrhoea/ runny nose	2	03OCT2020	30/8	1	No	O	NA/TC	R (10OCT2020)	N/N
1 1226 12261145 >55/ C459100	3^	NERV	Headache/ Headache	2	17SEP2020	15/1	1	No	O	NA/TC	R (17SEP2020)	N/N
1 1226 12261169 >55/ C459100	3^	NERV	Headache/ Headache	2	05SEP2020	2/1	2	Yes		NA/TC	R (05SEP2020)	N/N
1 1226 12261195		MUSC	Muscular weakness/ Lower limbs weakness	2	13OCT2020	40/C	1	No	O	NA/TC	RG	N/N
		NERV	Tremor/ Lower limbs tremor	2	13OCT2020	40/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1226 12261209	3^	GASTR	Nausea/ Nausea	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
		NERV	Headache/ Headache	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
>55/ C459100	3^	GASTR	Diarrhoea/ Diarrhea	2	14SEP2020	7/2	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261222 >55/ C459100	3^	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
1 1226 12261281 >55/ C459100	3^	GASTR	Abdominal pain upper/ stomachache	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
1 1226 12261283		GENRL	Chills/ chills	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
			Fatigue/ fatigue	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
		GASTR	Toothache/ toothache	2	03OCT2020	24/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1226 12261286	3^	GENRL	Injection site pain/ Pain at injection site	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1226 12261316	3^	GENRL	Pyrexia/ Fever	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N
		NERV	Headache/ Headache	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N
		GENRL	Pyrexia/ Fever (38.8 C)	2	11SEP2020	1/2	1	Yes		NA/TC/TCN	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
>55/ C459100 1 1226 12261317	3^	GENRL	Injection site pain/ Pain at injection site	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
>55/ C459100 1 1226 12261329	3^	GASTR	Diarrhoea/ diarrhea	2	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N
>55/ C459100 1 1226 12261335	3^	GENRL	Chills/ chills	2	10SEP2020	1/4	2	Yes		NA	R (13SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
		NERV	Headache/ headache	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
>55/ C459100 1 1226 12261342	3^	GENRL	Chills/ Chills	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
>55/ C459100 1 1226 12261366	3^	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/3	2	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1226 12261368	3^	MUSC	Injection site pain/ pain at injectin site	2	09SEP2020	1/3	2	Yes		NA/TC	R (11SEP2020)	N/N
			Myalgia/ muscle pain	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
			Headache/ headache	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		NERV	Headache/ headache	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1226 12261370	3^	EYE	Iritis/ left eye iritis	1	01SEP2020	12/15	1	No	O	NA/TC	R (15SEP2020)	N/N
>55/ C459100 1 1226 12261371	3^	GENRL	Injection site pain/ pain at injection site	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
		MUSC	Myalgia/ generalized muscle pain	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		MUSC	Arthralgia/ joint pain	2	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1226 12261381	3^	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	2/4	1	Yes		NA	R (28AUG2020)	N/N
>55/ C459100 1 1226 12261398	3^	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	2/3	1	Yes		NA	R (28AUG2020)	N/N
>55/ C459100 1 1226 12261419	3^	GENRL	Pyrexia/ Fever 38 C	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
		MUSC	Arthralgia/ Joint pain	2	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N
			Myalgia/ Muscle pain	2	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C459100 1 1226 12261462	3^	INFEC	Dental fistula/ dental fistula	2	OCT2020	13/C	2	No	O	NA	RG	N/N
		RESP	Sinus disorder/ Acute sinusopathy	2	20OCT2020	32/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1226 12261464	3^	MUSC	Myalgia/ Myalgia	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1226 12261473	3^	MUSC	Myalgia/ Muscle pain	2	20SEP2020	2/1	2	Yes		NA/TC	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1226 12261487	3^	GENRL	Fatigue/ fatigue	2	16SEP2020	2/3	2	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1226 12261499	3^	GENRL	Fatigue/ Tiredness	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
>55/ C459100 1 1226 12261510	3^	GENRL	Injection site pain/ Pain at injection site*		01SEP2020	1/4	1	Yes		NA	R (04SEP2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
>55/ C459100 1 1226 12261523	3^	GENRL	Injection site pain/ Pain at the injection site	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
		INFEC	Urinary tract infection/ urinary tract infection	2	03NOV2020	42/8	1	No	O	NA/TC	R (10NOV2020)	N/N
		METAB	Hypoglycaemia/ hypoglycemia	2	03NOV2020	42/1	3	No	O	NA/TC	R (03NOV2020)	N/N
>55/ C459100	3^	GENRL	Pyrexia/ Fever 38.6 C	2	26SEP2020	2/3	2	Yes		NA/TC	R (28SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261539		MUSC	Myalgia/ Muscle pain	2	26SEP2020	2/3	2	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C459100 1 1226 12261550	3^	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/4	1	Yes		NA/TC	R (27SEP2020)	N/N
			Pain/ Body pain	2	24SEP2020	1/4	1	Yes		NA/TC	R (27SEP2020)	N/N
		GENRL	Pyrexia/ fever (38.5 C)	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1226 12261552	3^	GENRL	Fatigue/ Tiredness	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1226 12261556	3^	GENRL	Pyrexia/ Fever (37.5 C)	1	06SEP2020	2/1	2	Yes		NA/TC	R (06SEP2020)	N/N
>55/ C459100 1 1226 12261605	3^	NERV	Headache/ Headache	1	08SEP2020	2/3	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1226 12261617	3^	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1226 12261638	3^	NERV	Headache/ Headache	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
>55/ C459100 1 1226 12261662	3^	GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ pain at injection site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		MUSC	Myalgia/ muscle pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1226 12261671	3^	GENRL	Injection site pain/ Pain at injection site	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1226 12261700	3^	GENRL	Injection site pain/ Pain at injection site	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1226 12261735	3^	GENRL	Injection site pain/ Pain at the injection site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1226 12261755	3^	NERV	Headache/ Headache	2	23OCT2020	18/3	2	No	O	NA/TC	R (25OCT2020)	N/N
>55/ C459100 1 1226 12261774	3^	GENRL	Pyrexia/ Fever (38 C)	2	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N
		MUSC	Myalgia/ muscle pain	2	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C459100 1 1226 12261783	3^	GENRL	Asthenia/ weakness	2	09OCT2020	3/1	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1226 12261786	3^	GENRL	Injection site pain/ Pain at the injection site	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		MUSC	Myalgia/ muscle pain	2	08OCT2020	2/1	2	Yes		NA/TC	R (08OCT2020)	N/N
		SKIN	Papule/ Papules on abdomen	2	10OCT2020	4/4	1	Yes		NA/TC	R (13OCT2020)	N/N
>55/ C459100 1 1226 12261816	3^	GENRL	Injection site erythema/ Erythema at injection site	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Injection site oedema/ Edema at injection site	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
			Injection site pain/ Pain at injection	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
		GENRL	Pyrexia/ fever (38.4C)	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
		GASTR	Toothache/ Toothache	2	19OCT2020	12/7	1	No	O	NA/TC	R (25OCT2020)	N/N
>55/ C459100 1 1226 12261822	3^	GENRL	Injection site pain/ Pain at injection site	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C459100 1 1226 12261825	3^	GENRL	Injection site pain/ pain at injection site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1226 12261837	3^	INFEC	Urinary tract infection/ Urinary tract infection	2	16OCT2020	8/4	2	No	O	NA/TC	R (19OCT2020)	N/N
>55/ C459100 1 1226 12261861	3^	GENRL	Injection site pain/ Pain at injection site	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
		VASC	Hypertension/ Systemic arterial hypertension	2	20OCT2020	13/C	1	No	O	NA/TC	RG	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Pain at the injection site	2	09OCT2020	1/3	2	Yes		NA	R (11OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12261862 >55/ C459100	3^	GENRL	Chills/ Chills	2	14OCT2020	1/1	2	Yes		NA/TC	R (14OCT2020)	N/N
1 1226 12261883		MUSC	Myalgia/ Muscle pain	2	14OCT2020	1/1	2	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C459100 1 1226 12261891	3^	GENRL	Injection site pain/ Pain at the injection site	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 1226 12261921	3^	GENRL	Injection site erythema/ redness at the injection site	2	20OCT2020	2/8	1	Yes		NA	R (27OCT2020)	N/N
			Injection site pain/ pain at injection site	2	20OCT2020	2/8	1	Yes		NA	R (27OCT2020)	N/N
>55/ C459100 1 1226 12261949	3^	GENRL	Chills/ chills	2	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
>55/ C459100 1 1226 12261986	3^	GASTR	Nausea/ nausea	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N
		GENRL	Chills/ chills	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Dizziness/ dizziness	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1226 12261991	3^	MUSC	Arthralgia/ Joint pain	1	07OCT2020	7/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1226 12262004	3^	GENRL	Injection site pain/ Pain at the injection site	1	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		GENRL	Pyrexia/ Fever (38 C)	1	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100 1 1226 12262009	3^	GENRL	Injection site pain/ Pain at the injection site	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N
			Pain/ Body ache	2	21OCT2020	1/3	2	Yes		NA	R (23OCT2020)	N/N
		NERV	Headache/ Headache	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N
>55/ C459100 1 1226 12262020	3^	GENRL	Pyrexia/ Fever 38 C	2	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Pain at the injection site	2	26OCT2020	1/C	1	Yes		NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12262057		INV	Body temperature increased/ Body temperature increased 37.5 C	2	26OCT2020	1/1	1	Yes		NA/TC	R (26OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	26OCT2020	1/C	1	Yes		NA/TC	RG	N/N
>55/ C459100 1 1226 12262066	3^	GENRL	Injection site erythema/ Redness at injection site	2	26OCT2020	1/2	2	Yes		NA	R (27OCT2020)	N/N
			Injection site pain/ Pain at injection site	2	26OCT2020	1/2	2	Yes		NA	R (27OCT2020)	N/N
			Pyrexia/ Fever (38.2 C)	2	26OCT2020	1/2	2	Yes		NA	R (27OCT2020)	N/N
		NERV	Headache/ Headache	2	26OCT2020	1/2	2	Yes		NA	R (27OCT2020)	N/N
>55/ C459100 1 1226 12262082	3^	INJ&P	Ligament sprain/ Sprained left ankle	1	13OCT2020	9/C	1	No	O	NA	RG	N/N
		GENRL	Chills/ Chills	2	27OCT2020	1/C	1	Yes		NA	RG	N/N
			Pyrexia/ Fever (38.0 C)	2	27OCT2020	1/C	1	Yes		NA	RG	N/N
		NERV	Headache/ Headache	2	28OCT2020	2/C	2	Yes		NA/TC	RG	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Pain at the injection site	1	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12262098 >55/ C459100	3^	MUSC	Myalgia/ Muscle pain	1	19OCT2020	12/2	1	No	O	NA	R (20OCT2020)	N/N
1 1226 12262109 >55/ C459100	3^	GENRL	Injection site pain/ pain at injection site	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
1 1226 12262118 >55/ C459100	3^	MUSC	Myalgia/ Myalgia	2	14OCT2020	1/C	1	Yes		NA/TC	N	N/Y
1 1229 12291005 >55/ C459100	3^	INJ&P	Fall/ Slip and accidental fall	1	10OCT2020	5/1	1	No	O	NA/TC	R (10OCT2020)	N/N
1 1229 12291125		MUSC	Arthralgia/ Left shoulder arthralgia	1	10OCT2020	5/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1230 12301016	3^	VASC	Hypertension/ Hypertension*		24SEP2020	1/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1230 12301025	3^	NEOPL	Penile neoplasm/ Penile Intra Epithelial Neoplasia	2	06NOV2020	22/C	3	No	O	NA	N	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1230 12301096	3^	MUSC	Myalgia/ Severe Muscle Pain	1	06OCT2020	6/3	1	No	O	NA	R (08OCT2020)	N/N
>55/ C459100 1 1230 12301119	3^	INJ&P	Arthropod bite/ Insect Bite	1	14OCT2020	12/3	1	No	O	NA/TC	R (16OCT2020)	N/N
>55/ C459100 1 1230 12301155	3^	MUSC	Myalgia/ Muscle Pain	2	27OCT2020	1/3	3	Yes		NA	R (29OCT2020)	N/N
>55/ C459100 1 1231 12311037	3^	GENRL	Fatigue/ Mild fatigue	1	17AUG2020	7/2	2	No	O	NA/TCN	R (18AUG2020)	N/N
>55/ C459100 1 1231 12311060	3^	SKIN	Pruritus/ Pruritus in legs and abdomen	1	21AUG2020	11/2	1	No	O	NA/TC	R (22AUG2020)	N/N
>55/ C459100 1 1231 12311090	3^	CARD	Palpitations/ palpitations	2	10SEP2020	9/3	1	No	O	NA	R (12SEP2020)	N/N
>55/ C459100 1 1231 12311133	3^	SKIN	Urticaria/ ACUTE HIVES	2	12NOV2020	71/C	1	No	O	NA/TC	RG	N/N
>55/ C459100	3^	GENRL	Asthenia/ Asthenia	1	21AUG2020	9/4	1	No	O	NA/TC	R (24AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12311146 >55/ C459100	3^	INFEC	Tooth infection/ Upper left second molar infection	2	19SEP2020	19/16	1	No	O	NA/TC	R (04OCT2020)	N/N
1 1231 12311155 >55/ C459100	3^	GASTR	Haemorrhoids/ Worsening of chronic hemorrhoids	2	10SEP2020	10/16	1	No	O	NA/TC	R (25SEP2020)	N/N
1 1231 12311163 >55/ C459100	3^	NERV	Migraine/ Worsening migraine	2	02SEP2020	2/5	2	No	O	NA/TC	R (06SEP2020)	N/N
1 1231 12311173 >55/ C459100	3^	GENRL	Injection site swelling/ Swelling on left arm at injection site	2	09SEP2020	8/4	1	Yes		NA	R (12SEP2020)	N/N
1 1231 12311184 >55/ C459100	3^	NERV	Headache/ headache	2	23SEP2020	20/1	2	No	O	NA/TC	R (23SEP2020)	N/N
1 1231 12311203 >55/ C459100	3^	GASTR	Odynophagia/ odynophagia	2	27SEP2020	24/3	1	No	O	NA	R (29SEP2020)	N/N
1 1231 12311236 >55/ C459100	3^	GASTR	Diverticulum intestinal/ Intestinal diverticulosis	2	06NOV2020	65/1	1	No	O	NA	R (06NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12311240	3^	RENAL	Haemorrhoids/ internal hemorrhoids	2	06NOV2020	65/1	1	No	O	NA	R (06NOV2020)	N/N
>55/ C459100 1 1231 12311240	3^	RENAL	Chronic kidney disease/ Worsening of chronic renal insufficiency	2	01OCT2020	30/8	1	No	O	NA/TC	R (08OCT2020)	N/N
>55/ C459100 1 1231 12311249	3^	INFEC	Gastroenteritis/ acute gastroenteritis	2	29SEP2020	28/1	2	No	O	NA/TCN	R (29SEP2020)	N/N
>55/ C459100 1 1231 12311254	3^	MUSC	Myalgia/ Myalgia generalized	2	15SEP2020	13/25	1	No	CD	NA	R (09OCT2020)	N/N
>55/ C459100 1 1231 12311278	3^	VASC	Hypertension/ episode of hypertension	2	27SEP2020	25/2	1	No	O	NA/TC	R (28SEP2020)	N/N
>55/ C459100 1 1231 12311318	3^	GENRL	Fatigue/ Fatigue	1	21AUG2020	7/3	1	No	O	NA	R (23AUG2020)	N/N
>55/ C459100 1 1231 12311326	3^	SKIN	Hyperhidrosis/ profus sweating	1	01SEP2020	18/1	1	No	O	NA	R (01SEP2020)	N/N
>55/ C459100 1 1231 12311382	3^	SKIN	Dermatitis/ Dermatitis on the scalp	1	31AUG2020	17/15	1	No	O	NA/TCN	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ headache	2	30SEP2020	27/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1231 12311400	3^	EYE	Conjunctival haemorrhage/ Conjunctival hemorrhage	1	20AUG2020	6/8	1	No	O	NA	R (27AUG2020)	N/N
>55/ C459100 1 1231 12311434	3^	SKIN	Rosacea/ Rosacea	2	14SEP2020	11/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1231 12311442	3^	INFEC	Tooth abscess/ Abscess in molar	2	01OCT2020	28/8	2	No	O	NA/TC	R (08OCT2020)	N/N
>55/ C459100 1 1231 12311498	3^	GENRL	Swelling/ SWELLING IN THE RIGHT AXILLA AND IPSILATERAL CERVICAL REGION	2	05OCT2020	29/C	1	No	O	NA	N	N/N
>55/ C459100 1 1231 12311514	3^	CARD	Palpitations/ daily exacerbation of palpitations	2	10SEP2020	4/3	1	No	O	NA/TC	R (12SEP2020)	N/N
>55/ C459100 1 1231 12311536	3^	PSYCH	Panic attack/ panic attack	2	14SEP2020	7/8	2	No	O	NA/TC	R (21SEP2020)	N/N
>55/ C459100 1 1231 12311563	3^	EYE	Eyelid haematoma/ left eye eyelid hematoma	1	25AUG2020	10/5	1	No	O	NA	R (29AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12311564	3^	GASTR	Irritable bowel syndrome/ irritable bowel syndrome	2	15SEP2020	9/17	1	No	O	NA/TC/TCN	R (01OCT2020)	N/N
>55/ C459100 1 1231 12311579	3^	INJ&P	Hand fracture/ closed fracture first phalanx right little finger	2	14SEP2020	8/32	1	No	O	NA/TC/TCN	R (15OCT2020)	N/N
		GASTR	Gastritis/ Acute gastritis	2	17OCT2020	41/18	3	No	O	NA/TC/TCN	R (03NOV2020)	Y/N
>55/ C459100 1 1231 12311589	3^	MUSC	Myalgia/ hands myalgia	1	28AUG2020	13/2	1	No	O	NA/TC	R (29AUG2020)	N/N
		SKIN	Rash/ Rash in lower limbs	2	24SEP2020	18/5	1	No	O	NA	R (28SEP2020)	N/N
>55/ C459100 1 1231 12311603	3^	GASTR	Nausea/ Nausea	1	16AUG2020	1/8	1	No	O	NA/TCN	R (23AUG2020)	N/N
		GASTR	Nausea/ Nausea	2	07SEP2020	1/3	1	No	O	NA/TCN	R (09SEP2020)	N/N
>55/ C459100 1 1231 12311610	3^	SKIN	Rash/ Skin rash in upper area of the back body, both sides of the neck and both sides of the abdomen	2	20SEP2020	13/10	1	No	O	NA/TC	R (29SEP2020)	N/N
>55/ C459100 1 1231 12311632	3^	INFEC	Cystitis/ Urinary Infection (Cystitis)	2	04OCT2020	27/2	1	No	O	NA/TC	R (05OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12311639	3^	MUSC	Myalgia/ muscle pain (right arm)	2	09SEP2020	3/14	1	No	O	NA/TC	R (22SEP2020)	N/N
		MUSC	Rotator cuff syndrome/ rotator cuff injury of the right shoulder	2	25OCT2020	49/C	2	No	O	NA/TC/TCN	RG	N/N
>55/ C459100 1 1231 12311675	3^	RESP	Dysphonia/ dysphonia	2	29OCT2020	52/2	1	No	O	NA	R (30OCT2020)	N/N
>55/ C459100 1 1231 12311706	3^	GASTR	Odynophagia/ odynophagia	1	03SEP2020	18/2	1	No	O	NA	R (04SEP2020)	N/N
		NERV	Headache/ headache	1	03SEP2020	18/2	1	No	O	NA/TC	R (04SEP2020)	N/N
>55/ C459100 1 1231 12311713	3^	GENRL	Injection site pain/ Left deltoid muscle injection site pain	2	08SEP2020	2/3	1	Yes		NA/TCN	R (10SEP2020)	N/N
>55/ C459100 1 1231 12311716	3^	INFEC	Vulvovaginitis/ vulvovaginitis	2	06OCT2020	29/9	1	No	O	NA/TC	R (14OCT2020)	N/N
>55/ C459100 1 1231 12311720	3^	MUSC	Pain in extremity/ Left arm pain	2	09SEP2020	1/2	2	No	O	NA/TC	R (10SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12311729	3^	MUSC	Back pain/ Back pain	1	22AUG2020	6/7	2	No	O	NA/TC	R (28AUG2020)	N/N
>55/ C459100 1 1231 12311744	3^	MUSC	Myalgia/ MYALGIAS IN UPPER LIMBS	2	25SEP2020	19/1	1	No	O	NA/TC	R (25SEP2020)	N/N
			Temporomandibular joint syndrome/ ARTHRALGIA ON TEMPOROMANDIBULAR JOINT	2	25SEP2020	19/1	1	No	O	NA/TC	R (25SEP2020)	N/N
>55/ C459100 1 1231 12311758	3^	SURG	Botulinum toxin injection/ botulinum toxin application	2	21SEP2020	15/1	1	No	O	NA	R (21SEP2020)	N/N
>55/ C459100 1 1231 12311775	3^	NERV	Headache/ headache	2	08SEP2020	2/26	2	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100 1 1231 12311808	3^	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	2	09OCT2020	33/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1231 12311814	3^	SKIN	Urticaria chronic/ chronic urticaria	1	18AUG2020	2/C	1	No	O	NA/TC	RG	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12311815	3^	NEOPL	Lymphoproliferative disorder/ REACTIVE LYMPHOID PROLIFERATION SUPRACLAVICULAR	1	06SEP2020	21/C	1	No	O	NA	N	N/N
		GENRL	Injection site pain/ Pain in injection site	1	18SEP2020	33/1	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1231 12311864	3^	SKIN	Urticaria/ generalized urticaria	2	03NOV2020	58/10	2	No	O	NA/TC	R (12NOV2020)	N/N
		SURG	Dental implantation/ DENTAL IMPLANT SURGERY	2	03NOV2020	58/1	2	No	O	NA/TC	R (03NOV2020)	N/N
>55/ C459100 1 1231 12311878	3^	ENDO	Thyroid mass/ nodules in thyroid gland	2	08OCT2020	31/C	1	No	O	NA	N	N/N
		METAB	Vitamin D deficiency/ Vitamin D deficiency	2	08OCT2020	31/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1231 12311912	3^	GASTR	Dental caries/ Caries in the upper left second molar	2	05OCT2020	18/C	2	No	O	NA	RG	N/N
		INFEC	Periodontitis/ periodontitis	2	14OCT2020	27/15	2	No	O	NA/TC	R (28OCT2020)	N/N
>55/ C459100 1 1231 12311914	3^	INFEC	Tooth infection/ Tooth infection (lower right molar)	1	20AUG2020	3/8	1	No	O	NA/TC	R (27AUG2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12311933	3^	SURG	Tooth extraction/ Extraction of teeth	2	05OCT2020	29/1	1	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C459100 1 1231 12311946	3^	NERV	Syncope/ Syncope	2	11SEP2020	4/2	3	No	O	NA/TC	R (12SEP2020)	Y/N
>55/ C459100 1 1231 12311948	3^	INJ&P	Fall/ fall from his own height	1	29AUG2020	12/4	1	No	O	NA/TC	R (01SEP2020)	N/N
		SKIN	Dermal cyst/ Left frontal epidermal cyst	2	10NOV2020	64/C	1	No	O	NA/TCN	RG	N/N
>55/ C459100 1 1231 12311956	3^	GENRL	Asthenia/ asthenia	2	08SEP2020	1/C	2	No	O	NA	N	N/N
>55/ C459100 1 1231 12311963	3^	VASC	Hypertension/ arterial hypertension	2	29OCT2020	51/14	1	No	O	NA/TC	R (11NOV2020)	N/N
>55/ C459100 1 1231 12311970	3^	INV	Blood glucose increased/ Elevated fasting blood glucose	2	20SEP2020	11/19	1	No	O	NA/TC	R (08OCT2020)	N/N
>55/ C459100 1 1231 12311978	3^	NERV	Headache/ headache	1	03SEP2020	17/11	1	No	O	NA	R (13SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Rhinorrhoea/ Rhinorrhea	1	03SEP2020	17/11	1	No	O	NA	R (13SEP2020)	N/N
>55/ C459100 1 1231 12311979	3^	INJ&P	Skin laceration/ Cutting wound on left index finger	1	06SEP2020	20/16	1	No	O	NA/TC/TCN	R (21SEP2020)	N/N
>55/ C459100 1 1231 12312000	3^	SKIN	Urticaria/ hives on the face and neck	2	16OCT2020	38/18	1	No	O	NA	R (02NOV2020)	N/N
>55/ C459100 1 1231 12312003	3^	MUSC	Arthralgia/ Pain in left hip	2	23SEP2020	17/4	2	No	O	NA/TC	R (26SEP2020)	N/N
			Joint swelling/ Swelling in left hip	2	23SEP2020	17/4	2	No	O	NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1231 12312006	3^	SURG	Dental implantation/ lower left premolar dental implant	2	24SEP2020	17/1	1	No	O	NA	R (24SEP2020)	N/N
		INFEC	Device related infection/ Dental Implant Infection	2	27SEP2020	20/9	1	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C459100 1 1231 12312025	3^	GASTR	Abdominal distension/ ABDOMINAL DISTENSION	1	02SEP2020	16/1	1	No	O	NA/TC	R (02SEP2020)	N/N
			Abdominal pain/ GENERAL ABDOMINAL PAIN	1	02SEP2020	16/1	1	No	O	NA/TC	R (02SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12312057	3^	INFEC	Periodontitis/ periodontitis	1	20AUG2020	3/8	2	No	O	NA/TC/TCN	R (27AUG2020)	N/N
>55/ C459100 1 1231 12312091	3^	INJ&P	Dental restoration failure/ Rupture of a cavity fix in a lower molar	2	17SEP2020	11/7	1	No	O	NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1231 12312092	3^	GASTR	Eiploic appendagitis/ Eiploic appendagitis	1	04SEP2020	18/8	1	No	O	NA/TC	R (11SEP2020)	N/N
>55/ C459100 1 1231 12312098	3^	INFEC	Gingivitis/ gingivitis	1	07SEP2020	21/1	1	No	O	NA/TC	R (07SEP2020)	N/N
>55/ C459100 1 1231 12312156	3^	METAB	Gout/ Worsening gout	1	27AUG2020	10/1	1	No	O	NA/TC	R (27AUG2020)	N/N
		INV	Body temperature increased/ Body temperature increased	1	29AUG2020	12/1	1	No	O	NA	R (29AUG2020)	N/N
>55/ C459100 1 1231 12312158	3^	GASTR	Abdominal pain/ Abdominal Pain	1	19AUG2020	2/7	3	Yes		NA/TC/TCN	R (25AUG2020)	N/N
			Diarrhoea/ Diarrhea. Over 6 loose stools per day.	1	19AUG2020	2/7	3	Yes		NA/TC/TCN	R (25AUG2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INV	Body temperature increased/ Body temperature increased	1	19AUG2020	2/7	3	Yes		NA/TC/TCN	R (25AUG2020)	N/N
>55/ C459100 1 1231 12312163	3^	GASTR	Diarrhoea/ diarrhea	2	09SEP2020	2/2	3	No	O	NA	R (10SEP2020)	N/N
>55/ C459100 1 1231 12312206	3^	GASTR	Odynophagia/ Odynophagia	2	10SEP2020	2/32	1	Yes		NA	R (11OCT2020)	N/N
		GENRL	Asthenia/ Asthenia	2	10SEP2020	2/32	1	Yes		NA	R (11OCT2020)	N/N
		NERV	Headache/ Headache	2	10SEP2020	2/32	1	Yes		NA	RS (11OCT2020)	N/N
>55/ C459100 1 1231 12312208	3^	VASC	Hypertension/ arterial hypertension associated with headache	2	15SEP2020	8/18	1	No	O	NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1231 12312220	3^	MUSC	Pain in extremity/ pain in left arm.	1	19AUG2020	1/3	3	No	O	NA	R (21AUG2020)	N/N
>55/ C459100 1 1231 12312223	3^	NERV	Headache/ headache	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
>55/ C459100 1 1231 12312234	3^	SKIN	Psoriasis/ Exacerbation of your underlying disease Psoriasis	2	11SEP2020	2/35	1	Yes		NA/TC	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GASTR	Glossitis/ Glossitis	2	15SEP2020	6/60	1	No	O	NA	R (13NOV2020)	N/N
>55/ C459100 1 1231 12312237	3^	NERV	Migraine with aura/ Migraine with aura	2	13SEP2020	3/17	2	No	O	NA/TC	R (29SEP2020)	N/N
>55/ C459100 1 1231 12312248	3^	IMMUN	Seasonal allergy/ exacerbation of seasonal allergic rhinitis	2	15SEP2020	6/17	1	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1231 12312256	3^	MUSC	Back pain/ low back pain	2	15SEP2020	7/2	2	No	O	NA/TC	R (16SEP2020)	N/N
>55/ C459100 1 1231 12312265	3^	NERV	Dizziness/ dizziness	2	14SEP2020	6/4	1	No	O	NA	R (17SEP2020)	N/N
		SURG	Dental implantation/ dental implant	2	25SEP2020	17/1	1	No	O	NA/TC	R (25SEP2020)	N/N
		METAB	Vitamin D deficiency/ hypovitaminosis d	2	30OCT2020	52/1	1	No	O	NA/TC	R (30OCT2020)	N/N
>55/ C459100 1 1231 12312277	3^	GENRL	Asthenia/ asthenia	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
		INV	Body temperature increased/ increased body temperature oral cavity register 37.2	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ headache	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1231 12312318	3^	GASTR	Toothache/ left upper molar pain	2	24SEP2020	16/5	1	No	O	NA/TC	R (28SEP2020)	N/N
>55/ C459100 1 1231 12312332	3^	REPRO	Genital erythema/ Nonspecific glans erythema	2	15SEP2020	8/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1231 12312380	3^	INFEC	Urinary tract infection/ Urinary tract infection	2	24SEP2020	18/19	1	No	O	NA/TC	R (12OCT2020)	N/N
>55/ C459100 1 1231 12312453	3^	GASTR	Diarrhoea/ diarrhea	1	06SEP2020	18/1	2	No	O	NA	R (06SEP2020)	N/N
>55/ C459100 1 1231 12312459	3^	INJ&P	Ligament sprain/ Left foot sprain	2	28SEP2020	18/8	1	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C459100 1 1231 12312463	3^	MUSC	Arthralgia/ Left omalgia with irradiation to the left pectoral.	2	10OCT2020	19/6	1	No	O	NA	R (15OCT2020)	N/N
>55/ C459100 1 1231 12312470	3^	GASTR	Toothache/ tooth pain	2	12SEP2020	3/29	1	No	O	NA/TC	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12312496	3^	INFEC	Tooth infection/ odontogenic infection	2	12SEP2020	3/11	1	No	O	NA/TC	R (22SEP2020)	N/N
		NERV	Headache/ headache	2	12SEP2020	3/29	1	No	O	NA/TC	R (10OCT2020)	N/N
		MUSC	Back pain/ ACUTE LOW BACK PAIN	1	03SEP2020	15/3	1	No	O	NA/TC	R (05SEP2020)	N/N
>55/ C459100 1 1231 12312498	3^	MUSC	Back pain/ acute low back pain	1	28SEP2020	40/2	2	No	O	NA/TC	R (29SEP2020)	N/N
		NERV	Headache/ Headache	2	05OCT2020	26/2	2	No	O	NA	R (06OCT2020)	N/N
		VASC	Hypertension/ Arterial hypertension	2	05OCT2020	26/2	1	No	O	NA	R (06OCT2020)	N/N
>55/ C459100 1 1231 12312527	3^	MUSC	Neck pain/ cervicalgia	2	28SEP2020	20/16	2	No	O	NA/TC/TCN	R (13OCT2020)	N/N
>55/ C459100 1 1231 12312556	3^	INJ&P	Skin laceration/ Left hand thumb and index finger cut	2	24SEP2020	14/2	1	No	O	NA/TC/TCN	R (25SEP2020)	N/N
>55/ C459100 1 1231 12312568	3^	GENRL	Injection site pain/ Injection site pain.	2	11SEP2020	2/14	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12312614	3^	INFEC	Urinary tract infection/ Urinary infection	1	02SEP2020	14/14	1	No	O	NA/TC	R (15SEP2020)	N/N
>55/ C459100 1 1231 12312646	3^	METAB	Hyperuricaemia/ Hyperuricemia	1	02SEP2020	14/31	1	No	O	NA/TC/TCN	R (02OCT2020)	N/N
>55/ C459100 1 1231 12312700	3^	GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	17/2	1	No	O	NA	R (25SEP2020)	N/N
>55/ C459100 1 1231 12312703	3^	SKIN	Rash/ left axilar skin rash	2	17SEP2020	8/2	1	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1231 12312722	3^	NERV	Headache/ headache	2	01OCT2020	24/3	1	No	O	NA	R (03OCT2020)	N/N
>55/ C459100 1 1231 12312749	3^	INJ&P	Burns first degree/ First-degree burn	2	10OCT2020	28/14	2	No	O	NA/TC/TCN	R (23OCT2020)	N/N
			Burns second degree/ Second-degree burn	2	10OCT2020	28/14	2	No	O	NA/TC/TCN	R (23OCT2020)	N/N
>55/ C459100 1 1231 12312756	3^	MUSC	Arthralgia/ Right omalgia	2	12NOV2020	64/C	1	No	O	NA/TCN	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12312768	3^	GENRL	Pyrexia/ fever 37.4 c.	2	19SEP2020	9/1	1	No	O	NA/TC	R (19SEP2020)	N/N
		NERV	Headache/ headache	2	19SEP2020	9/1	1	No	O	NA/TC	R (19SEP2020)	N/N
>55/ C459100 1 1231 12312820	3^	MUSC	Back pain/ low back pain	2	15SEP2020	5/3	1	No	O	NA/TC	R (17SEP2020)	N/N
		EAR	Meniere's disease/ Menieres disease exacerbation	2	20SEP2020	10/32	1	No	O	NA	R (21OCT2020)	N/N
>55/ C459100 1 1231 12312841	3^	INJ&P	Facial bones fracture/ Nose fracture	1	21AUG2020	1/16	2	No	O	NA/TC/TCN	R (05SEP2020)	N/N
>55/ C459100 1 1231 12312863	3^	INFEC	Sinusitis/ SINUSITIS	1	21AUG2020	1/15	3	No	O	NA/TC	R (04SEP2020)	N/N
		MUSC	Temporomandibular joint syndrome/ Temporomandibular joint dysfunction	1	04SEP2020	15/15	2	No	O	NA/TC	R (18SEP2020)	N/N
		MUSC	Exostosis/ Nasal septum spur	2	30SEP2020	6/37	2	No	O	NA/TCN	R (05NOV2020)	N/N
		RESP	Nasal turbinate hypertrophy/ hypertrophy of nasal turbinates.	2	30SEP2020	6/37	2	No	O	NA/TCN	R (05NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Trigeminal neuralgia/ TRIGEMINAL NEURALGIA	2	07OCT2020	13/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1231 12312887	3^	GASTR	Oesophageal spasm/ esophageal spasm	2	15SEP2020	7/1	2	No	O	NA/TC	R (15SEP2020)	N/N
		SKIN	Rash pruritic/ Pruritic rash on both legs gluteal region and both arms	2	22OCT2020	44/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1231 12312893	3^	INV	Lumbar puncture/ Spinal Puncture in the lumbar sacral region	2	06OCT2020	26/1	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1231 12312902	3^	GENRL	Pyrexia/ febrile syndrome	2	30SEP2020	21/1	1	No	O	NA/TC	R (30SEP2020)	N/N
>55/ C459100 1 1231 12312909	3^	INJ&P	Skin laceration/ Dirty cutting wound in right upper limb	2	04OCT2020	24/2	1	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C459100 1 1231 12312915	3^	SURG	Lens extraction/ Phacoemulsification of the right eye	1	31AUG2020	11/1	1	No	O	NA/TC/TCN	R (31AUG2020)	N/N
>55/ C459100 1 1231 12312945	3^	GASTR	Gastritis/ Gastritis	1	30AUG2020	10/4	1	No	CND	NA/TC	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12312967	3^	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	07OCT2020	27/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C459100 1 1231 12312980	3^	MUSC	Back pain/ low back pain	1	07SEP2020	18/2	2	No	O	NA	R (08SEP2020)	N/N
			Neck pain/ cervicalgia	1	07SEP2020	18/4	2	No	O	NA	R (10SEP2020)	N/N
		NERV	Paraesthesia/ Intermittent paresthesia in hands	1	07SEP2020	18/2	1	No	O	NA	R (08SEP2020)	N/N
>55/ C459100 1 1231 12312993	3^	ENDO	Thyroid mass/ thyroid nodules	2	07OCT2020	27/C	1	No	O	NA	N	N/N
>55/ C459100 1 1231 12312997	3^	METAB	Diabetes mellitus inadequate control/ Dysregulation of your insulin- dependent Diabetes Mellitus with poor management of blood glucose lev.	2	21SEP2020	12/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1231 12313073	3^	MUSC	Arthralgia/ interphalangeal joint arthralgias of both hands	2	16SEP2020	6/7	2	No	O	NA/TC	R (22SEP2020)	N/N
>55/ C459100 1 1231 12313089	3^	INJ&P	Fall/ Fall from own height	2	16OCT2020	37/1	2	No	O	NA/TC/TCN	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Joint injury/ RIGHT KNEE TRAUMA	2	16OCT2020	37/1	2	No	O	NA/TC/TCN	R (16OCT2020)	N/N
			Tibia fracture/ right tibia anterior tuberosity fracture	2	16OCT2020	37/19	2	No	O	NA/TC/TCN	R (03NOV2020)	N/N
>55/ C459100 1 1231 12313114	3^	SURG	Tooth extraction/ tooth extraction	1	03SEP2020	13/1	1	No	O	NA/TC	R (03SEP2020)	N/N
>55/ C459100 1 1231 12313118	3^	MUSC	Myalgia/ myalgia	2	12OCT2020	33/5	1	No	O	NA/TC	R (16OCT2020)	N/N
>55/ C459100 1 1231 12313150	3^	MUSC	Myalgia/ myalgia in left lower limb	2	22SEP2020	10/20	1	Yes		NA	R (11OCT2020)	N/N
>55/ C459100 1 1231 12313208	3^	RENAL	Dysuria/ Dysuria	2	17SEP2020	8/8	1	No	O	NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1231 12313230	3^	SKIN	Rash/ rash on face and neck. etiology unknown	2	18SEP2020	9/3	1	No	O	NA/TC	R (20SEP2020)	N/N
>55/ C459100 1 1231 12313267	3^	SKIN	Rash maculo-papular/ Itchy, erythematous maculopapular skin rash involving posterior neck, left arm, and trunk	1	25AUG2020	4/1	1	Yes		NA/TC	R (25AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12313323	3^	MUSC	Neck pain/ NECK PAIN	2	20SEP2020	8/33	1	No	O	NA	R (22OCT2020)	N/N
>55/ C459100 1 1231 12313344	3^	GASTR	Diarrhoea/ Diarrhea	2	22SEP2020	10/3	1	No	O	NA	R (24SEP2020)	N/N
>55/ C459100 1 1231 12313354	3^	BLOOD	Anaemia/ exacerbation of chronic anemia	2	23SEP2020	11/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1231 12313359	3^	MUSC	Intervertebral disc protrusion/ Worsening of herniated discs	1	23SEP2020	32/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1231 12313371	3^	REPRO	Benign prostatic hyperplasia/ benign prostatic hyperplasia	2	08OCT2020	26/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1231 12313391	3^	MUSC	Back pain/ LOW BACK PAIN	1	07SEP2020	16/2	1	No	O	NA/TC/TCN	R (08SEP2020)	N/N
>55/ C459100 1 1231 12313397	3^	INJ&P	Limb injury/ puncture injury to left index finger	2	15SEP2020	5/10	2	No	O	NA/TC	R (24SEP2020)	N/N
		PSYCH	Sleep disorder/ Worsening of sleep disorder	2	22SEP2020	12/42	2	No	O	NA/TC	R (02NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12313401	3^	INJ&P	Road traffic accident/ Mild car accident	2	13OCT2020	29/1	1	No	O	NA	R (13OCT2020)	N/N
>55/ C459100 1 1231 12313410	3^	SKIN	Rash pruritic/ Itchy rash on forehead and right buttock	2	01OCT2020	18/4	1	No	O	NA	R (04OCT2020)	N/N
>55/ C459100 1 1231 12313411	3^	GASTR	Anal pruritus/ Anal itching	2	05OCT2020	23/12	1	No	O	NA	R (16OCT2020)	N/N
>55/ C459100 1 1231 12313418	3^	SKIN	Dermatitis allergic/ skin allergy	2	29SEP2020	16/3	1	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 1231 12313478	3^	GENRL	Injection site pain/ injection site pain	1	23AUG2020	1/2	1	Yes		NA/TC	R (24AUG2020)	N/Y
>55/ C459100 1 1231 12313480	3^	MUSC	Back pain/ Low back pain	1	30SEP2020	39/4	1	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100 1 1231 12313485	3^	GENRL	Injection site pain/ Injection site pain	1	23AUG2020	1/3	1	Yes		NA	R (25AUG2020)	N/N
>55/ C459100	3^	BLOOD	Lymphadenopathy/ LEFT INFRACLAVICULAR	2	17SEP2020	3/8	1	No	O	NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12313496		VASC	ADENOPATHY, 5 mm IN DIAMETER. Hypertension/ Arterial hypertension	2	24OCT2020	40/2	1	No	O	NA	R (25OCT2020)	N/N
>55/ C459100 1 1231 12313552	3^	GASTR	Parotid duct obstruction/ PAROTID BLOCKAGE	2	19SEP2020	7/4	2	No	O	NA/TC	R (22SEP2020)	N/N
		INFEC	Parotitis/ ACUTE PAROTITIS	2	19SEP2020	7/4	2	No	O	NA/TC	R (22SEP2020)	N/N
>55/ C459100 1 1231 12313573	3^	NERV	Headache/ HEADACHE	2	09OCT2020	26/2	2	No	O	NA/TCN	R (10OCT2020)	N/N
		MUSC	Neck pain/ positional cervicalgia	2	12OCT2020	29/5	1	No	O	NA	R (16OCT2020)	N/N
>55/ C459100 1 1231 12313600	3^	EAR	Vertigo/ Worsening of vertiginous syndrome	2	07OCT2020	25/10	2	No	O	NA	R (16OCT2020)	N/N
>55/ C459100 1 1231 12313604	3^	INFEC	Tooth infection/ dental infection	1	12SEP2020	21/13	1	No	O	NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1231 12313608	3^	INJ&P	Meniscus injury/ exacerbation of previous pathology, knee meniscus injury.	2	15SEP2020	5/6	2	No	O	NA/TC	R (20SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Carpal tunnel syndrome/ Possible Carpal Tunnel Syndrome under study	2	16SEP2020	6/C	2	No	O	NA	RG	N/N
>55/ C459100 1 1231 12313621	3^	RESP	Pulmonary mass/ Right pulmonary nodule	2	24SEP2020	10/C	3	No	O	NA/TCN	UNK	Y/N
>55/ C459100 1 1231 12313625	3^	INJ&P	Fall/ Fall from your own height	1	05SEP2020	13/1	1	No	O	NA	R (05SEP2020)	N/N
		MUSC	Arthralgia/ Hip joint pain	1	05SEP2020	13/44	1	No	O	NA	R (18OCT2020)	N/N
>55/ C459100 1 1231 12313628	3^	GASTR	Odynophagia/ Odynophagia	1	01SEP2020	9/10	2	No	O	NA/TC	R (10SEP2020)	N/N
		NERV	Headache/ headache	1	01SEP2020	9/2	1	No	O	NA/TC	RS (02SEP2020)	N/N
		RESP	Rhinorrhoea/ Rhinorrhea	1	01SEP2020	9/35	1	No	O	NA/TC	R (05OCT2020)	N/N
>55/ C459100 1 1231 12313651	3^	VASC	Hypertension/ High blood pressure records*		24AUG2020	1/47	1	No	O	NA/TC/TCN	R (09OCT2020)	N/N
>55/ C459100 1 1231 12313652	3^	NERV	Headache/ Headache	1	25AUG2020	2/2	1	Yes		NA/TC	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12313674	3^	SKIN	Rash pruritic/ Pruritic rash on periocular region	1	25AUG2020	2/2	1	Yes		NA/TC	R (26AUG2020)	N/N
		EYE	Keratitis/ Keratitis	2	22SEP2020	10/C	1	No	O	NA/TC	RG	N/N
		SKIN	Eczema/ Scalp eczema	2	08OCT2020	26/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1231 12313688	3^	RESP	Pneumonitis/ Non-specific Pneumonitis	2	29SEP2020	17/C	2	No	O	NA	RG	Y/N
		RESP	Emphysema/ Panlobar emphysema	2	09OCT2020	27/C	1	No	O	NA	N	N/N
		INFEC	Sialoadenitis/ Left submaxillary sialadenitis	2	03NOV2020	52/7	2	No	O	NA/TC	R (09NOV2020)	N/N
>55/ C459100 1 1231 12313741	3^	Produ	Device breakage/ detachment of lower left premolar crown	2	09OCT2020	27/8	1	No	O	NA/TCN	R (16OCT2020)	N/N
		SKIN	Rash/ Rash on cheeks and forehead	2	21SEP2020	8/3	1	No	O	NA/TC	R (23SEP2020)	N/N
		SKIN	Rash/ rash on cheeks and forehead	2	11OCT2020	28/5	1	No	O	NA	R (15OCT2020)	N/N
>55/ C459100 1 1231 12313744	3^	GENRL	Injection site pain/ Local pain at injection site	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ headache	1	24AUG2020	1/3	1	No	O	NA	R (26AUG2020)	N/N
>55/ C459100 1 1231 12313748	3^	METAB	Dyslipidaemia/ Dyslipidemia	2	15OCT2020	32/C	1	No	O	NA/TC/TCN	RG	N/N
>55/ C459100 1 1231 12313754	3^	GENRL	Injection site pain/ pain at the injection site	1	01SEP2020	9/45	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1231 12313755	3^	NERV	Facial paresis/ right peripheral facial hemiparesis	2	16OCT2020	32/15	2	No	O	NA	R (30OCT2020)	N/N
>55/ C459100 1 1231 12313775	3^	INFEC	Tooth infection/ Odontogenic infection of the upper left second molar.	2	13OCT2020	31/7	1	No	O	NA/TC	R (19OCT2020)	N/N
>55/ C459100 1 1231 12313783	3^	MUSC	Intervertebral disc protrusion/ Worsening lumbar disc herniation	1	10SEP2020	18/64	3	No	O	NA/TC/TCN	R (12NOV2020)	Y/N
>55/ C459100 1 1231 12313807	3^	GENRL	Injection site pain/ LOCAL PAIN AT THE INJECTION SITE	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
		GENRL	Pyrexia/ FEVER	1	27AUG2020	3/2	1	Yes		NA/TC	R (28AUG2020)	N/N
		MUSC	Myalgia/ Generalized myalgia	1	27AUG2020	3/2	1	Yes		NA/TC	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12313817	3^	MUSC	Back pain/ Low back pain	2	01OCT2020	16/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1231 12313833	3^	CARD	Arrhythmia/ ARRHYTHMIA	2	19OCT2020	37/1	2	No	O	NA/TC	R (19OCT2020)	N/N
>55/ C459100 1 1231 12313849	3^	GENRL	Injection site pain/ injection site pain	2	13SEP2020	1/2	3	Yes		NA/TC	R (14SEP2020)	N/N
>55/ C459100 1 1231 12313860	3^	VASC	Hypertension/ Arterial hypertension	1	17SEP2020	24/C	1	No	O	NA	N	N/N
>55/ C459100 1 1231 12313894	3^	INJ&P	Muscle rupture/ Right hamstring muscle tear	2	16OCT2020	32/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1231 12313897	3^	SKIN	Pruritus/ generalized itching	1	08SEP2020	15/55	1	No	O	NA/TC	R (01NOV2020)	N/N
>55/ C459100 1 1231 12313920	3^	MUSC	Back pain/ Low back pain	2	26SEP2020	12/4	2	No	O	NA/TCN	R (29SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Pain at the injection site	1	08SEP2020	15/8	1	Yes		NA/TC	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12313938 >55/ C459100	3^	SKIN	Eczema/ Scalp eczema	2	16SEP2020	4/41	1	No	O	NA/TC	R (26OCT2020)	N/N
1 1231 12313947 >55/ C459100	3^	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE	1	25AUG2020	1/8	1	Yes		NA	R (01SEP2020)	N/N
1 1231 12313952 >55/ C459100	3^	METAB	Hypercholesterolaemia/ Worsening of Hypercholesterolemia	2	15OCT2020	33/4	2	No	O	NA/TC/TCN	R (18OCT2020)	N/N
1 1231 12313961 >55/ C459100	3^	NERV	Haemorrhagic stroke/ Hemorrhagic stroke	2	27SEP2020	15/2	4	No	O	NA/TC/W	F (28SEP2020)	Y/N
1 1231 12313972 >55/ C459100	3^	CARD	Palpitations/ palpitations	2	01OCT2020	17/12	1	No	O	NA/TC	R (12OCT2020)	N/N
1 1231 12313997 >55/ C459100	3^	CARD	Acute coronary syndrome/ Acute coronary syndrome	2	08NOV2020	55/C	3	No	O	NA/TC/TCN	RG	Y/N
1 1231 12314001 >55/ C459100	3^	NERV	Tremor/ left hand tremor	1	31AUG2020	7/C	1	No	O	NA	N	N/N
1 1231 12314014												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12314019	3^	GASTR	Dyspepsia/ Worsening of heartburn	1	27AUG2020	3/8	1	No	O	NA/TC	R (03SEP2020)	N/N
		MUSC	Back pain/ Back pain	1	27AUG2020	3/22	1	No	O	NA	R (17SEP2020)	N/N
>55/ C459100 1 1231 12314025	3^	NERV	Headache/ Headache	2	01OCT2020	16/1	1	No	O	NA	R (01OCT2020)	N/N
		VASC	Hypertension/ Exacerbation of arterial hypertension	2	01OCT2020	16/1	1	No	O	NA/TC	R (01OCT2020)	N/N
		MUSC	Back pain/ LOWER BACK PAIN	2	20OCT2020	35/5	1	No	O	NA	R (24OCT2020)	N/N
>55/ C459100 1 1231 12314035	3^	CARD	Angina pectoris/ Angina Pectoris	2	20SEP2020	7/5	3	No	O	NA/TC/TCN	R (24SEP2020)	Y/N
		PSYCH	Anxiety/ Anxiety Crisis	2	29SEP2020	16/1	2	No	O	NA	R (29SEP2020)	N/N
>55/ C459100 1 1231 12314044	3^	INJ&P	Tooth fracture/ Molar fracture	2	10OCT2020	28/5	1	No	O	NA/TC	R (14OCT2020)	N/N
>55/ C459100 1 1231 12314054	3^	SKIN	Pruritus/ pruritus on torax and abdomen zone	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Pyrexia/ fever	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
		NERV	Headache/ headache	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
>55/ C459100 1 1231 12314060	3^	PSYCH	Anxiety/ Anxiety crisis	1	25SEP2020	32/4	1	No	O	NA	R (28SEP2020)	N/N
>55/ C459100 1 1231 12314063	3^	NERV	Tension headache/ Morning Tension Headache	2	15OCT2020	31/6	1	No	O	NA	R (20OCT2020)	N/N
>55/ C459100 1 1231 12314089	3^	MUSC	Back pain/ worsening low back pain	1	10SEP2020	16/6	1	No	O	NA/TC	R (15SEP2020)	N/N
>55/ C459100 1 1231 12314103	3^	MUSC	Muscle contracture/ left arm and shoulder muscle contracture	1	05SEP2020	11/6	2	No	O	NA/TC/TCN	R (10SEP2020)	N/N
>55/ C459100 1 1231 12314139	3^	INFEC	Tooth infection/ dental infection	2	12OCT2020	29/3	1	No	O	NA/TC	R (14OCT2020)	N/N
>55/ C459100 1 1231 12314149	3^	MUSC	Myalgia/ myalgia in lower limbs	1	30AUG2020	5/23	2	Yes		NA	R (21SEP2020)	N/N
		MUSC	Arthralgia/ ankles arthralgia	2	28SEP2020	15/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Arthralgia/ hip arthralgia	2	28SEP2020	15/C	1	No	O	NA/TC	N	N/N
			Arthralgia/ knees arthralgia	2	28SEP2020	15/C	1	No	O	NA/TC	N	N/N
			Arthralgia/ spinal column arthralgia	2	28SEP2020	15/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1231 12314164	3^	INJ&P	Thermal burn/ right forearm and hand burn	1	11SEP2020	17/38	1	No	O	NA/TC	RS (18OCT2020)	N/N
>55/ C459100 1 1231 12314187	3^	GENRL	Chills/ isolated chills	1	09SEP2020	15/2	1	No	O	NA	R (10SEP2020)	N/N
>55/ C459100 1 1231 12314197	3^	MUSC	Arthralgia/ Hip joint pain	2	11NOV2020	59/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1231 12314214	3^	GASTR	Abdominal pain/ Nonspecific abdominal pain	2	15OCT2020	32/1	1	No	O	NA	R (15OCT2020)	N/N
		GASTR	Abdominal pain/ Abdominal pain	2	28OCT2020	45/C	1	No	O	NA	N	N/N
>55/ C459100 1 1231 12314216	3^	INFEC	Appendicitis/ Acute Appendicitis	1	05SEP2020	11/5	3	No	O	NA/TC/TCN	R (09SEP2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		EAR	Vertigo/ Vertigo	1	07OCT2020	43/C	2	No	O	NA	N	N/N
		VASC	Orthostatic hypotension/ orthostatic hypotension	1	11OCT2020	47/2	1	No	O	NA	R (12OCT2020)	N/N
>55/ C459100 1 1231 12314231	3^	INFEC	Laryngitis/ Worsening of chronic laryngitis.	2	09OCT2020	26/6	1	No	O	NA/TC	R (14OCT2020)	N/N
>55/ C459100 1 1231 12314234	3^	GENRL	Injection site pain/ Local pain at injection site	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
>55/ C459100 1 1231 12314255	3^	BLOOD	Lymphadenopathy/ Painful left axillary adenopathy	2	19SEP2020	4/4	1	No	O	NA/TC	R (22SEP2020)	N/N
>55/ C459100 1 1231 12314258	3^	GENRL	Asthenia/ Asthenia	1	27AUG2020	2/1	2	Yes		NA/TC	R (27AUG2020)	N/N
>55/ C459100 1 1231 12314281	3^	NERV	Dizziness/ LIPOTHYMIA(DIZZINESS)	2	15SEP2020	2/1	2	No	O	NA/TC/TCN	R (15SEP2020)	N/N
>55/ C459100 1 1231 12314289	3^	NERV	Headache/ headache	2	23SEP2020	10/5	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100	3^	GASTR	Dyspepsia/ Postprandial dyspepsia	2	09OCT2020	25/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12314299 >55/ C459100	3^	GENRL	Asthenia/ ASTHENIA	1	02SEP2020	8/4	1	No	O	NA	R (05SEP2020)	N/N
1 1231 12314313 >55/ C459100	3^	INFEC	Urinary tract infection/ urinary infection	2	20SEP2020	6/5	1	No	O	NA/TC	R (24SEP2020)	N/N
1 1231 12314332 >55/ C459100	3^	INFEC	Urinary tract infection/ urinary infection	2	20OCT2020	36/10	1	No	O	NA/TC	R (29OCT2020)	N/N
1 1231 12314378 >55/ C459100	3^	SKIN	Dermatitis allergic/ skin allergy that was located in the neck and between the eyebrows	2	02OCT2020	16/5	1	No	O	NA/TC	R (06OCT2020)	N/N
1 1231 12314384 >55/ C459100	3^	UNC	BROWNISH EJACULATION@@/ brownish ejaculation	2	13NOV2020	58/C	1	No	O	NA	N	N/N
1 1231 12314401 >55/ C459100	3^	SKIN	Psoriasis/ exacerbation of his psoriasis manifests itself in both legs, both elbows, gluteal region and back	2	23SEP2020	8/22	2	No	O	NA/TC	R (14OCT2020)	N/N
1 1231 12314412 >55/ C459100	3^	NERV	Presyncope/ Vasovagal hypotension	2	21OCT2020	35/1	1	No	O	NA	R (21OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12314413	3^	INFEC	Tooth infection/ Dental infection	2	06NOV2020	41/5	1	No	O	NA/TC	R (10NOV2020)	N/N
>55/ C459100 1 1231 12314428	3^	NERV	Headache/ headache.	2	09OCT2020	25/1	1	No	O	NA	R (09OCT2020)	N/N
>55/ C459100 1 1231 12314432	3^	GENRL	Chills/ chills	1	27AUG2020	1/1	3	Yes		NA	R (27AUG2020)	N/N
		NERV	Headache/ Headache	1	27AUG2020	1/1	3	Yes		NA	R (27AUG2020)	N/N
		RESP	Rhinorrhoea/ Rhinorrhea	1	27AUG2020	1/1	3	Yes		NA	R (27AUG2020)	N/N
>55/ C459100 1 1231 12314446	3^	MUSC	Back pain/ low back pain	2	10OCT2020	25/4	1	No	O	NA/TC	R (13OCT2020)	N/N
>55/ C459100 1 1231 12314453	3^	SURG	Lacrimal duct procedure/ Tear duct closure for dry eye.	2	17OCT2020	32/1	1	No	O	NA/TCN	R (17OCT2020)	N/N
>55/ C459100 1 1231 12314458	3^	VASC	Hypertension/ Exacerbation of arterial hypertension	1	14SEP2020	19/4	1	No	O	NA/TC	R (17SEP2020)	N/N
>55/ C459100	3^	MUSC	Back pain/ back pain	1	29AUG2020	3/3	1	No	O	NA/TC	R (31AUG2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12314469 >55/ C459100	3^	INFEC	Onychomycosis/ worsening of onychomycosis	1	31AUG2020	5/C	1	No	O	NA/TC	RG	N/N
1 1231 12314495 >55/ C459100	3^	GASTR	Odynophagia/ ODYNOPHAGIA	1	11SEP2020	16/2	1	No	O	NA	R (12SEP2020)	N/N
1 1231 12314518 >55/ C459100	3^	MUSC	Back pain/ low back pain	1	29AUG2020	3/3	1	No	O	NA/TC/TCN	R (31AUG2020)	N/N
1 1231 12314561		MUSC	Muscle spasms/ Cramps in left lower limb	2	17SEP2020	3/4	2	No	O	NA/TC	R (20SEP2020)	N/N
			Myalgia/ Moderate general myalgia	2	17SEP2020	3/4	2	Yes		NA/TC	R (20SEP2020)	N/N
>55/ C459100 1 1231 12314567	3^	GENRL	Injection site pain/ local pain in the left arm at injection site	2	16SEP2020	2/4	3	Yes		NA/TC	R (19SEP2020)	N/N
>55/ C459100 1 1231 12314579	3^	INJ&P	Skin abrasion/ excoriation on the thumb of the right hand	2	03NOV2020	50/1	1	No	O	NA/TC	R (03NOV2020)	N/N
>55/ C459100	3^	GASTR	Dry mouth/ dry mouth	1	11SEP2020	16/C	1	No	O	NA	N	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12314657		SKIN	Rash/ skin rash on the face	1	12SEP2020	17/3	1	No	O	NA	R (14SEP2020)	N/N
		GENRL	Face oedema/ edema on face	2	21SEP2020	7/6	1	No	O	NA/TC/TCN	R (26SEP2020)	N/N
		REPRO	Pruritus genital/ ITCHING OF GENITALS	2	21SEP2020	7/6	1	No	O	NA/TC	R (26SEP2020)	N/N
		SKIN	Pruritus/ ITCHING OF THE SCALP	2	21SEP2020	7/6	1	No	O	NA/TC	R (26SEP2020)	N/N
>55/ C459100 1 1231 12314668	3^	INFEC	Tooth infection/ Odontogenic infection	2	28SEP2020	13/6	1	No	O	NA/TC/TCN	R (03OCT2020)	N/N
>55/ C459100 1 1231 12314675	3^	NERV	Hypoaesthesia/ increase of frequency of hypoesthesia at the level of the left upper limb	1	30AUG2020	3/24	1	No	O	NA	R (22SEP2020)	N/N
>55/ C459100 1 1231 12314681	3^	NERV	Myoclonus/ chin myoclonus	1	05SEP2020	9/66	1	No	O	NA	R (09NOV2020)	N/N
>55/ C459100 1 1231 12314690	3^	GASTR	Gastroesophageal reflux disease/ exacerbation of gastroesophageal reflux	2	01OCT2020	16/29	1	No	O	NA/TC	R (29OCT2020)	N/N
>55/ C459100	3^	METAB	Hyperglycaemia/ Hyperglycemia	2	05OCT2020	20/6	1	No	O	NA/TC/TCN	R (10OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12314707 >55/ C459100 1 1231 12314807	3^	VASC	Hypertensive crisis/ hypertensive crisis	1	08SEP2020	12/2	3	No	O	NA/TC/TCN	R (09SEP2020)	N/N
		PSYCH	Panic attack/ panic attack	1	14SEP2020	18/1	1	No	O	NA	R (14SEP2020)	N/N
>55/ C459100 1 1231 12314879	3^	SKIN	Rash/ localised back exanthema	2	15OCT2020	30/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1231 12314891	3^	PSYCH	Depression/ Acute Depressive Syndrome	2	05NOV2020	51/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1231 12314898	3^	INFEC	Pneumonia/ community acquired pneumonia	2	03OCT2020	18/13	3	No	O	NA/TC/TCN	R (15OCT2020)	Y/N
>55/ C459100 1 1231 12314911	3^	NERV	Headache/ Headache	1	29AUG2020	2/18	1	Yes		NA/TC	R (15SEP2020)	N/N
>55/ C459100 1 1231 12314916	3^	METAB	Hypertriglyceridaemia/ Hypertriglyceridemia	1	12SEP2020	16/29	1	No	O	NA/TC	R (10OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12314953	3^	INFEC	Tooth infection/ dental infection	2	18OCT2020	31/10	1	No	O	NA/TC	R (27OCT2020)	N/N
		SKIN	Rash pruritic/ Pruritic rash in lower back, abdomen and neck.	2	30OCT2020	43/7	1	No	O	NA	R (05NOV2020)	N/N
>55/ C459100 1 1231 12314960	3^	GENRL	Axillary pain/ left armpit pain	2	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
		GENRL	Application site pruritus/ itching at the product application site	2	20SEP2020	3/6	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1231 12314961	3^	GENRL	Induration/ local induration	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
			Injection site erythema/ erythema at injection site	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
			Pain/ pain	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
>55/ C459100 1 1231 12314966	3^	VASC	Hypertension/ arterial hypertension	2	20SEP2020	5/28	1	No	O	NA/TC	R (17OCT2020)	N/N
>55/ C459100 1 1231 12314972	3^	RESP	Bronchospasm/ Worsening bronchospasm	1	29AUG2020	2/18	2	No	O	NA/TC	R (15SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12314973	3^	NERV	Headache/ Mild and intermittent headache. Retro ocular location.	1	29AUG2020	2/6	1	Yes		NA/TC	R (03SEP2020)	N/N
>55/ C459100 1 1231 12314988	3^	MUSC	Muscle spasms/ Righth masseter muscle spasm	2	17SEP2020	2/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1231 12314993	3^	INFEC	Herpes zoster/ herpez zooster in left orbital region	2	19SEP2020	2/12	1	No	O	NA/TC	R (30SEP2020)	N/N
>55/ C459100 1 1231 12315004	3^	EAR	Vertigo positional/ benign paroxysmal positional vertigo	2	21SEP2020	4/3	2	No	O	NA/TC/TCN	R (23SEP2020)	N/N
>55/ C459100 1 1231 12315010	3^	VASC	Hypertension/ HYPERTENSION	1	31AUG2020	4/3	2	No	O	NA/TC	R (02SEP2020)	N/N
>55/ C459100 1 1231 12315017	3^	GASTR	Toothache/ Toothache	1	05SEP2020	9/8	1	No	O	NA/TC	R (12SEP2020)	N/N
>55/ C459100 1 1231 12315018	3^	MUSC	Back pain/ Low back pain	1	16SEP2020	20/1	2	No	O	NA/TC	R (16SEP2020)	N/N
>55/ C459100	3^	BLOOD	Lymphadenopathy/ Left cervical adenopathy	2	21SEP2020	6/4	1	No	O	NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12315023 >55/ C459100	3^	GASTR	Irritable bowel syndrome/ Irritable bowel syndrome exacerbation	2	06OCT2020	21/4	2	No	O	NA/TC/TCN	R (09OCT2020)	N/N
1 1231 12315025 >55/ C459100	3^	MUSC	Groin pain/ groin pain	1	01SEP2020	5/35	2	No	O	NA	R (05OCT2020)	N/N
1 1231 12315030 >55/ C459100	3^	SKIN	Pruritus/ Itching with small vesicles, macules and scabs on the hands and feet.	2	18SEP2020	3/C	1	No	O	NA/TC	N	N/N
1 1231 12315032 >55/ C459100	3^	INFEC	Gastroenteritis/ gastroenteritis	1	06SEP2020	10/5	1	No	O	NA	R (10SEP2020)	N/N
1 1231 12315044 >55/ C459100	3^	GENRL	Chills/ Chills	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
1 1231 12315049 >55/ C459100	3^	GENRL	Pyrexia/ Fever	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
1 1231 12315051 >55/ C459100	3^	SURG	Tooth extraction/ tooth extraction	2	05OCT2020	20/1	2	No	O	NA/TC/TCN	R (05OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12315058	3^	GENRL	Injection site pain/ Pain at injection site	1	30AUG2020	2/2	1	Yes		NA	R (31AUG2020)	N/N
>55/ C459100 1 1231 12315106	3^	VASC	Hypertension/ arterial hypertension	2	20SEP2020	4/2	2	No	O	NA/TC	R (21SEP2020)	N/N
>55/ C459100 1 1231 12315148	3^	NERV	Paraesthesia/ paresthesias of the right forearm	2	12OCT2020	26/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1231 12315159	3^	SKIN	Dermatitis exfoliative/ desquamative dermatitis	1	01SEP2020	4/58	1	No	O	NA	R (28OCT2020)	N/N
>55/ C459100 1 1231 12315237	3^	INFEC	Gastroenteritis/ GASTROENTERITIS	1	05SEP2020	8/8	2	No	O	NA/TC	R (12SEP2020)	N/N
>55/ C459100 1 1231 12315250	3^	GENRL	Asthenia/ asthenia	2	20SEP2020	2/2	2	Yes		NA	R (21SEP2020)	N/N
>55/ C459100 1 1231 12315273	3^	HEPAT	Biliary colic/ Biliary colic	2	22SEP2020	6/3	3	No	O	NA/TC	R (24SEP2020)	N/N
>55/ C459100	3^	NERV	Burning sensation/ Lower limbs burning sensation.	2	13OCT2020	27/25	1	No	O	NA	R (06NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12315290 >55/ C459100	3^	GENRL	Peripheral swelling/ Pain and swelling in the first phalanx of your right index finger	2	28OCT2020	42/C	1	No	O	NA	RG	N/N
1 1231 12315293 >55/ C459100	3^	GENRL	Reactogenicity event/ local reactogenicity	2	17SEP2020	1/8	2	Yes		NA/TC	R (24SEP2020)	N/N
1 1231 12315305 >55/ C459100	3^	MUSC	Back pain/ Low back pain	2	24SEP2020	8/4	1	No	O	NA/TC	R (27SEP2020)	N/N
1 1231 12315315 >55/ C459100	3^	SKIN	Pruritus/ mild itching	1	29AUG2020	1/23	1	No	O	NA	R (20SEP2020)	N/N
1 1231 12315336 >55/ C459100	3^	IMMUN	Allergy to arthropod bite/ Allergic reaction secondary to insect bite	2	08NOV2020	53/C	1	No	O	NA/TC	RG	N/N
1 1231 12315341 >55/ C459100	3^	EAR	Tinnitus/ TINNITUS IN LEFT EAR	1	09SEP2020	12/C	1	No	O	NA	RG	N/N
1 1231 12315345 >55/ C459100	3^	REPRO	Breast calcifications/ Microcalcifications in the right breast	2	10OCT2020	24/C	1	No	O	NA	N	N/N
1 1231 12315366												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12315382	3^	SURG	Tooth extraction/ tooth extraction	1	15SEP2020	17/16	1	No	O	NA/TC	R (30SEP2020)	N/N
>55/ C459100 1 1231 12315384	3^	GASTR	Haemorrhoidal haemorrhage/ Hemorrhoidal bleeding	2	20SEP2020	2/32	1	No	O	NA/TC/TCN	R (21OCT2020)	N/N
>55/ C459100 1 1231 12315404	3^	RENAL	Haematuria/ macroscopic haematuria	1	31AUG2020	2/33	1	No	O	NA/TC	R (02OCT2020)	N/N
		RENAL	Haematuria/ Gross hematuria	2	10OCT2020	3/12	1	No	O	NA	R (21OCT2020)	N/N
>55/ C459100 1 1231 12315410	3^	EYE	Cataract/ bilateral cataract	2	23SEP2020	6/C	1	No	O	NA	N	N/N
>55/ C459100 1 1231 12315455	3^	MUSC	Back pain/ low back pain	1	14SEP2020	16/1	2	No	O	NA/TC	R (14SEP2020)	N/N
>55/ C459100 1 1231 12315507	3^	INFEC	Bone abscess/ abscessed lesion in left iliac fossa	2	29SEP2020	12/15	1	No	O	NA/TC/TCN	R (13OCT2020)	N/N
>55/ C459100 1 1231 12315509	3^	ENDO	Hypothyroidism/ hypothyroidism	2	13OCT2020	25/31	1	No	O	NA/TC	R (12NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Relative ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1231 12315510	3^	METAB	Insulin resistance/ Resistance to the insulin	2	13OCT2020	25/31	1	No	O	NA/TC/TCN	R (12NOV2020)	N/N
>55/ C459100 1 1231 12315510	3^	GASTR	Abdominal pain upper/ epigastralgia	1	07SEP2020	9/12	1	No	O	NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1231 12315520	3^	METAB	Type 2 diabetes mellitus/ Diabetes type 2	1	11SEP2020	13/1	1	No	O	NA/TC/TCN	R (11SEP2020)	N/N
>55/ C459100 1 1231 12315520	3^	INV	Body temperature increased/ Body temperature increased	1	06SEP2020	8/4	1	No	O	NA/TC	R (09SEP2020)	N/N
>55/ C459100 1 1231 12315571	3^	MUSC	Muscle contracture/ pectoral muscle contracture	1	07SEP2020	8/4	2	No	O	NA/TC/TCN	R (10SEP2020)	N/N
>55/ C459100 1 1231 12315598	3^	NERV	Dysgeusia/ dysgeusia	1	06SEP2020	7/2	1	No	O	NA	R (07SEP2020)	N/N
>55/ C459100 1 1231 12315607	3^	MUSC	Back pain/ Moderate low back pain	2	24SEP2020	6/5	2	No	O	NA	R (28SEP2020)	N/N
>55/ C459100 1 1231 12315617	3^	RESP	Epistaxis/ Acute epistaxis of the right nostril	2	09OCT2020	21/1	2	No	O	NA/TCN	R (09OCT2020)	N/N
>55/ C459100	3^	INJ&P	Animal bite/ dog bite injury in left outer thigh	1	18SEP2020	19/8	2	No	O	NA/TC	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1231 12315625 >55/ C459100 1 1231 12315632	3^	INFE	Suspected COVID-19/ Probable COVID-19 illness	2	17OCT2020	29/C	4	No	O	NA/TC	N	Y/N
		GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux disease	2	30OCT2020	42/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1231 12315653	3^	NERV	Ischaemic stroke/ Ischemic stroke	2	12OCT2020	24/5	2	No	O	NA/TC	R (16OCT2020)	Y/N
>55/ C459100 1 1231 12315665	3^	NERV	Headache/ Mild Headache	1	31AUG2020	1/2	1	No	O	NA	R (01SEP2020)	N/N
		SKIN	Pruritus/ Generalized Pruritus	1	31AUG2020	1/2	1	No	O	NA	R (01SEP2020)	N/N
			Rash erythematous/ Generalized pruritic erythematous rash	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
			Rash/ Facial Rash	1	31AUG2020	1/2	1	No	O	NA	R (01SEP2020)	N/N
>55/ C459100 1 1231 12315683	3^	INFE	Periodontitis/ periodontitis	2	15OCT2020	27/3	1	No	O	NA/TC/TCN	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1232 12321203	3^	MUSC	Back pain/ Backache	1	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
		MUSC	Back pain/ Backache	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
>55/ C459100 1 1235 12351086	3^	GENRL	Fatigue/ fatigue	2	06OCT2020	1/11	2	Yes		NA	R (16OCT2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
>55/ C459100 1 1235 12351095	3^	GASTR	Diarrhoea/ Diarrhea	1	24SEP2020	9/2	1	No	CD	NA/TC	R (25SEP2020)	N/N
>55/ C459100 1 1235 12351120	3^	MUSC	Myalgia/ localized myalgia	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
>55/ C459100 1 1235 12351123	3^	GASTR	Vomiting/ vomiting	2	12OCT2020	1/12	1	Yes		NA/TC	R (23OCT2020)	N/N
		GENRL	Chills/ chills	2	12OCT2020	1/12	2	Yes		NA/TC	R (23OCT2020)	N/N
		GENRL	Pyrexia/ fever	2	12OCT2020	1/12	2	Yes		NA/TC	R (23OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Arthralgia/ joint aches	2	12OCT2020	1/12	1	Yes		NA/TC	R (23OCT2020)	N/N
		RESP	Dyspnoea/ shortness of breath	2	12OCT2020	1/12	2	No	O	NA/TC	R (23OCT2020)	N/N
			Oropharyngeal pain/ sore throat	2	12OCT2020	1/12	1	No	O	NA/TC	R (23OCT2020)	N/N
>55/ C459100 1 1235 12351139	3^	GENRL	Pyrexia/ Pyrexia	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
>55/ C459100 1 1235 12351148	3^	GENRL	Fatigue/ Fatigue	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1235 12351150	3^	INFEC	Urinary tract infection/ urinary tract infection	1	10OCT2020	17/11	2	No	O	NA/TC	R (20OCT2020)	N/N
>55/ C459100 1 1241 12411008	3^	GENRL	Injection site pain/ Injection site pain	1	07AUG2020	1/1	1	Yes		NA	R (07AUG2020)	N/Y
		NERV	Headache/ Headache	1	07AUG2020	1/4	1	Yes		NA	R (10AUG2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Injection site burning	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411015 >55/ C459100	3^	GENRL	Injection site pain/ injection site pain	1	11AUG2020	1/1	1	Yes		NA	R (11AUG2020)	N/Y
1 1241 12411035 >55/ C459100	3^	INFEC	Conjunctivitis/ Conjunctivitis	1	18AUG2020	6/28	1	No	O	NA/TC	R (14SEP2020)	N/N
1 1241 12411092 >55/ C459100	3^	GENRL	Injection site swelling/ Injection site swelling	1	13AUG2020	1/1	1	Yes		NA	R (13AUG2020)	N/Y
1 1241 12411105 >55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/Y
1 1241 12411182 >55/ C459100	3^	MUSC	Back pain/ Backache	1	04SEP2020	19/1	1	No	O	NA/TC	R (04SEP2020)	N/N
1 1241 12411187 >55/ C459100	3^	NERV	Dysgeusia/ Bitter taste	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
1 1241 12411196 >55/ C459100	3^	GASTR	Diarrhoea/ Diarrhea	2	11SEP2020	2/4	2	Yes		NA	R (14SEP2020)	N/N
1 1241 12411306												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1241 12411320	3^	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
>55/ C459100 1 1241 12411322	3^	NERV	Headache/ Headache	1	28AUG2020	10/2	1	No	O	NA/TC	R (29AUG2020)	N/N
>55/ C459100 1 1241 12411340	3^	NERV	Headache/ Headache	1	21AUG2020	2/2	1	No	O	NA/TC	R (22AUG2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
>55/ C459100 1 1241 12411352	3^	NERV	Headache/ Headache	2	02OCT2020	22/1	1	No	O	NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1241 12411394	3^	GENRL	Injection site pain/ Injection site pain	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/Y
>55/ C459100 1 1241 12411479	3^	INFEC	Otitis media acute/ Acute otitis media	2	10OCT2020	26/11	1	No	O	NA	R (20OCT2020)	N/N
>55/ C459100 1 1241 12411485	3^	GENRL	Pyrexia/ Fever	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11241 12411498	3^	GENRL	Pyrexia/ Fever	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 11241 12411523	3^	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 11241 12411545	3^	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
			Injection site pain/ Injection site pain	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
		NERV	Headache/ Headache	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N
		INJ&P	Fall/ Fall from own height	2	23SEP2020	2/1	3	No	O	NA	R (23SEP2020)	N/N
		NERV	Dizziness/ Dizziness	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N
			Dizziness/ Lipothymia (Dizziness)	2	23SEP2020	2/1	3	No	O	NA	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1241 12411550	3^	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
			Injection site pain/ Injection site pain	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1241 12411554	3^	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ Prostration	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1241 12411585	3^	GENRL	Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
>55/ C459100 1 1241 12411615	3^	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1241 12411623	3^	GENRL	Fatigue/ Tiredness	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1241 12411628	3^	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1241 12411628	3^	GENRL	Fatigue/ Fatigue	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1241 12411643	3^	HEPAT	Cholecystitis/ Acute cholecystitis with cholelithiasis	2	24OCT2020	31/5	3	No	O	NA/TC	R (28OCT2020)	Y/N
>55/ C459100 1 1241 12411644	3^	GENRL	Chills/ Chills	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
			Fatigue/ Fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ Headache	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
>55/ C459100 1 1241 12411670	3^	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	2/3	2	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1241 12411671	3^	INFEC	Vulvovaginal candidiasis/ Vaginal candidiasis	1	20SEP2020	11/4	1	No	O	NA/TC	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INFEC	Urinary tract infection/ Urinary tract infection	2	20OCT2020	22/7	1	No	O	NA/TC	R (26OCT2020)	N/N
>55/ C459100 1 1241 12411675	3^	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1241 12411676	3^	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
			Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1241 12411704	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1241 12411711	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
>55/ C459100 1 1241 12411728	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
>55/ C459100 1 1241 12411732	3^	GENRL	Injection site swelling/ Injection site swelling	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1241 12411746	3^	MUSC	Arthralgia/ Arthralgia in the left knee	1	22SEP2020	7/6	2	Yes		NA/TC	R (27SEP2020)	N/N
			Myalgia/ Muscle pains in left shoulder	1	22SEP2020	7/6	2	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C459100 1 1241 12411748	3^	GENRL	Fatigue/ Fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 1241 12411752	3^	GASTR	Nausea/ Nausea	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ Headache	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	07OCT2020	2/2	2	Yes		NA/TCN	R (08OCT2020)	N/N
		GENRL	Pain/ Body pain	2	07OCT2020	2/1	2	Yes		NA/TC	R (07OCT2020)	N/N
>55/ C459100 1 1241 12411761	3^	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100	3^	MUSC	Myalgia/ Myalgia	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411794 >55/ C459100 1 1241 12411796	3^	GENRL	Chills/ Chills	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		NERV	Headache/ Headache	1	19SEP2020	3/3	2	Yes		NA/TC	R (21SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	22SEP2020	6/3	2	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1241 12411821	3^	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
>55/ C459100 1 1241 12411825	3^	INFEC	Pyelonephritis acute/ ACUTE PYELINEPHRITIS	2	02NOV2020	26/C	2	No	O	NA/TC	RG	Y/N
		BLOOD	Hypochromic anaemia/ HYPOCHROMIC ANEMIA / MICROCYTIC	2	04NOV2020	28/C	1	No	O	NA	N	N/N
>55/ C459100 1 1241 12411852	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/3	2	Yes		NA/TC	R (20SEP2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12411896		GENRL	Fatigue/ Fatigue	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	11OCT2020	3/1	1	Yes		NA	R (11OCT2020)	N/N
>55/ C459100 1 1241 12411902	3^	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1241 12411910	3^	GENRL	Chills/ Chills	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
			Fatigue/ Fatigue	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
>55/ C459100 1 1241 12411934	3^	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N
>55/ C459100 1 1241 12411938	3^	GENRL	Chills/ Chills	2	07OCT2020	1/4	2	Yes		NA	R (10OCT2020)	N/N
			Injection site pain/ Injection site pain	2	07OCT2020	1/4	2	Yes		NA	R (10OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	07OCT2020	1/4	2	Yes		NA	R (10OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1241 12411959	3^	MUSC	Back pain/ Backache	2	07OCT2020	1/1	1	No	O	NA/TC	R (07OCT2020)	N/N
>55/ C459100 1 1241 12412021	3^	GASTR	Abdominal pain lower/ Abdominal pain in hypogastrium	2	23OCT2020	5/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1241 12412042	3^	GENRL	Chills/ Chills	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ Fatigue	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pain/ Injection site pain	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Injection site pruritus/ Injection site itching	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
			Injection site swelling/ Injection site swelling	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		NERV	Headache/ Headache	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
>55/ C459100 1 1241 12412075	3^	GENRL	Chills/ Chills	1	01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N
			Injection site pain/ Injection site pain	1	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1241 12412125	3^	GENRL	Injection site pain/ Injection site pain	1	03OCT2020	2/4	1	Yes		NA/TCN	R (06OCT2020)	N/N
>55/ C459100 1 1246 12461035	3^	GENRL	Chest pain/ Chest pain	2	10NOV2020	22/3	3	No	O	NA/TCN	R (12NOV2020)	Y/N
>55/ C459100 1 1247 12471039	3^	INJ&P	Fall/ Fall	1	13OCT2020	19/1	2	No	O	NA	R (13OCT2020)	N/N
>55/ C459100 1 1247 12471093	3^	INFEC	Rib fracture/ Right 9th rib fractured Nasopharyngitis/ Common cold*	1	13OCT2020	19/C	2	No	O	NA/TC	N	N/N
		PSYCH	Insomnia/ Insomnia	1	23OCT2020	18/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1247 12471094	3^	INFEC	Oral herpes/ Herpes Simplex of the lip	1	09OCT2020	11/7	1	No	O	NA/TC	R (15OCT2020)	N/N
>55/ C459100 1 1247 12471135	3^	NERV	Cerebral infarction/ Left Middle Cerebral Artery Infarct	1	21OCT2020	22/C	3	No	O	P/TC/TCN	N	Y/N
		NERV	Cerebellar infarction/ Chronic cerebellar infarcts	1	23OCT2020	24/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Cerebral atrophy/ Cerebral atrophy	1	23OCT2020	24/C	1	No	O	NA	N	N/N
>55/ C459100 1 1248 12481002	3^	GENRL	Injection site pain/ Injection Site Reaction (pain)	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
>55/ C459100 1 1248 12481020	3^	GENRL	Injection site pain/ Injection site reaction (pain)	1	29AUG2020	2/3	2	Yes		NA	R (31AUG2020)	N/N
>55/ C459100 1 1248 12481021	3^	MUSC	Pain in extremity/ Left arm pain	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
>55/ C459100 1 1248 12481027	3^	GENRL	Chills/ Chills	2	20SEP2020	1/2	1	Yes		NA	R (21SEP2020)	N/N
			Injection site pain/ Injection site Pain	2	20SEP2020	1/2	1	Yes		NA/TC	R (21SEP2020)	N/N
			Pain/ Bodyaches	2	20SEP2020	1/2	1	Yes		NA/TC	R (21SEP2020)	N/N
>55/ C459100 1 1248 12481029	3^	GENRL	Injection site pain/ Left Arm Pain at Injection Site Reaction	1	29AUG2020	1/4	2	Yes		NA	R (01SEP2020)	N/Y
>55/ C459100 1 1248 12481040	3^	GENRL	Injection site pruritus/ Injection Site Reaction Itching Mild	1	31AUG2020	2/3	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site swelling/ Injection Site Reaction Swelling	1	31AUG2020	2/3	1	No	O	NA	R (02SEP2020)	N/N
			Injection site pain/ Injection site (pain)	2	20SEP2020	1/1	1	Yes		NA/TC	R (20SEP2020)	N/N
			Fatigue/ Fatigue	2	21SEP2020	2/1	1	Yes		NA/TC	R (21SEP2020)	N/N
>55/ C459100 1 1248 12481041	3^	GASTR	Diarrhoea/ Diarrhea	1	02SEP2020	4/1	2	No	O	NA	R (02SEP2020)	N/N
>55/ C459100 1 1248 12481047	3^	GENRL	Injection site pain/ Injection Site Reaction Pain	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
			Injection site pain/ Injection Site Reaction(pain)	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
			Fatigue/ Fatigue	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
>55/ C459100 1 1248 12481049	3^	GENRL	Injection site haemorrhage/ Injection Site Reaction(ecchymosis)	2	19SEP2020	2/23	1	Yes		NA	R (11OCT2020)	N/N
			Injection site mass/ Injection Site Reaction (Lump/Knot)	2	19SEP2020	2/7	1	Yes		NA	R (25SEP2020)	N/N
			NERV	Dizziness/ Dizziness	2	13OCT2020	26/C	1	No	O	NA	RG

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1248 12481058	3^	MUSC	Arthralgia/ Right Knee Pain	1	12SEP2020	12/7	1	No	O	NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1248 12481083	3^	GASTR	Abdominal pain upper/ Stomachache	1	23SEP2020	19/2	1	No	O	NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1248 12481084	3^	GENRL	Chills/ Chills	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
			Injection site pain/ Injection Site pain	2	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
			Pain/ Body aches	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ Headache	2	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C459100 1 1248 12481090	3^	GENRL	Injection site pain/ Right Arm soreness(Injection Site)	1	06SEP2020	1/2	1	Yes		NA	R (07SEP2020)	N/N
>55/ C459100 1 1248 12481105	3^	NERV	Burning sensation/ Burning Sensation in Leg	1	28SEP2020	20/2	1	No	O	NA	R (29SEP2020)	N/N
>55/ C459100 1 1248 12481120	3^	NERV	Cerebrovascular accident/ Mild Stroke	1	23SEP2020	13/C	3	No	O	NA	RG	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1248 12481124	3^	GENRL	Injection site pain/ injection Site Pain	2	03OCT2020	1/2	2	Yes		NA/TC	RS (04OCT2020)	N/N
>55/ C459100 1 1248 12481128	3^	NERV	Headache/ Headache	1	12SEP2020	1/2	1	Yes		NA/TC	R (13SEP2020)	N/N
>55/ C459100 1 1248 12481132	3^	GENRL	Fatigue/ Tiredness	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N
			Injection site pain/ Injection Site Reaction Pain	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/Y
		METAB	Decreased appetite/ Decreased Appetite	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	15SEP2020	4/3	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	1	15SEP2020	4/3	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C459100 1 1248 12481139	3^	NERV	Headache/ Headache	1	13SEP2020	2/2	1	Yes		NA/TC	R (14SEP2020)	N/N
>55/ C459100 1 1248 12481140	3^	GENRL	Injection site pain/ injection site reaction-Left upper arm pain	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1248 12481142	3^	INV	Body temperature increased/ Increase Temperature	1	14SEP2020	2/2	1	Yes		NA	R (15SEP2020)	N/N
		NERV	Headache/ Headache	1	14SEP2020	2/1	1	Yes		NA	R (14SEP2020)	N/N
>55/ C459100 1 1248 12481148	3^	GENRL	Injection site pain/ Injection site Pain	1	13SEP2020	1/4	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1248 12481163	3^	NERV	Headache/ Headache (R sided headache around R eye)	1	03OCT2020	20/3	1	No	O	NA/TC	R (05OCT2020)	N/N
		INFEC	Brain abscess/ Brain abscess	2	10OCT2020	6/C	4	No	O	NA/TCN	RG	Y/N
			Sinusitis/ Sinusitis	2	10OCT2020	6/C	3	No	O	NA/TCN	RG	N/N
>55/ C459100 1 1248 12481184	3^	GENRL	Injection site reaction/ Injection Site Reaction	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1248 12481207	3^	GENRL	Injection site pain/ Left Arm Pain at injection	1	18SEP2020	1/33	1	Yes		NA	R (20OCT2020)	N/N
>55/ C459100 1 1248 12481241	3^	UNC	PAIN IN SITE OF INJECTION RIGHT ARM@@/ Pain in site of injection right arm	2	14OCT2020	2/C	1	Yes				N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1251 12511028	3^	INJ&P	Foot fracture/ broken right foot	2	23SEP2020	13/C	3	No	O	NA/TC/TCN	RG	N/N
>55/ C459100 1 1251 12511050	3^	VASC	Hypertension/ exacerbation of hypertension	1	04SEP2020	11/C	3	No	O	NA	RG	Y/N
>55/ C459100 1 1251 12511055	3^	MUSC	Arthralgia/ B/L knee soreness	1	28AUG2020	4/1	1	Yes		NA	R (28AUG2020)	N/N
>55/ C459100 1 1251 12511056	3^	GENRL	Chills/ Chills	1	26AUG2020	2/1	1	No	O	NA	R (26AUG2020)	N/N
>55/ C459100 1 1251 12511063	3^	GASTR	Nausea/ nausea	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ chills	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ headache	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1251 12511087	3^	MUSC	Arthralgia/ worsening of left shoulder pain	1	02SEP2020	3/C	2	Yes		NA/TC	N	N/N
		MUSC	Exostosis/ Bone spur left shoulder	1	06OCT2020	37/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1251 12511110	3^	GENRL	Vaccination site swelling/ Left arm swelling at injection site after flu shot	2	15OCT2020	23/4	1	No	O	NA/TC	R (18OCT2020)	N/N
>55/ C459100 1 1251 12511116	3^	MUSC	Myalgia/ muscle aches	1	10SEP2020	8/5	1	Yes		NA	R (14SEP2020)	N/N
>55/ C459100 1 1251 12511151	3^	EYE	Retinal detachment/ Detached Retina	2	09OCT2020	10/6	3	No	O	NA/TCN	RS (14OCT2020)	N/N
>55/ C459100 1 1251 12511158	3^	GENRL	Injection site pain/ Pain at Injection Site Left Deltoid	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
			Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
			Malaise/ Malaise	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
>55/ C459100 1 1251 12511167	3^	GENRL	Chills/ chills	2	06OCT2020	2/1	1	Yes		NA/TCN	R (06OCT2020)	N/N
		RESP	Oropharyngeal pain/ sore throat	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1251 12511186	3^	SKIN	Rash/ Rash Chin Elbows Knees Neck	2	11OCT2020	3/C	1	No	O	NA/TC	N	N/N
		UNC	TONGUE AND THROAT SWELLING@@/ Tongue and throat swelling	2	30OCT2020	22/9	2	Yes		NA/TC	R (07NOV2020)	N/N
>55/ C459100 1 1251 12511203	3^	GASTR	Diarrhoea/ Diarrhea	1	28SEP2020	6/1	1	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C459100 1 1254 12541004	3^	GENRL	Injection site pain/ injection site soreness	1	26AUG2020	1/2	2	Yes		NA	R (27AUG2020)	N/N
		GENRL	Fatigue/ fatigue	1	31AUG2020	6/5	2	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 1 1254 12541010	3^	GASTR	Diarrhoea/ diarrhea	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
		GASTR	Diarrhoea/ diarrhea	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1254 12541011	3^	GENRL	Fatigue/ Fatigue	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		GENRL	Chills/ chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1254 12541012	3^	SKIN	Fatigue/ fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
			Pain/ bodyache	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N	
			Rash/ LEFT LOWER EXTREMITY RASH	1	02SEP2020	7/18	1	No	O	NA	R (19SEP2020)	N/N	
			Blister/ ONE BLISTER (2.5 INCHES BELOW INJECTION SITE)	2	16SEP2020	1/4	1	No	O	NA	R (19SEP2020)	N/N	
>55/ C459100 1 1254 12541014	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
>55/ C459100 1 1254 12541018	3^	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/6	2	Yes		NA	R (02SEP2020)	N/N	
			RESP	Rhinorrhoea/ Runny Nose	1	31AUG2020	4/3	1	Yes		NA	R (02SEP2020)	N/N
			GENRL	Fatigue/ fatigue	2	19SEP2020	1/4	2	Yes		NA	R (22SEP2020)	N/N
				Pain/ bodyache	2	19SEP2020	1/4	1	Yes		NA/TC	R (22SEP2020)	N/N
			NERV	Headache/ headache	2	20SEP2020	2/3	1	Yes		NA/TC	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1254 12541025	3^	GENRL	Injection site pain/ SORENESS OF INJECTION SITE	2	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 1 1254 12541026	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
>55/ C459100 1 1254 12541037	3^	GENRL	Injection site pain/ Injection site pain	1	29AUG2020	1/2	1	Yes		NA	R (30AUG2020)	N/N
>55/ C459100 1 1254 12541047	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Chills/ chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ soreness at injection site	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
			Pain/ bodyache	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		VASC	Hypertension/ hypertension	2	02OCT2020	10/C	2	No	O	NA/TC	RG	N/N
		MUSC	Psoriatic arthropathy/ worsening of psoriatic arthritis	2	09OCT2020	17/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1254 12541048	3^	GASTR	Gastroesophageal reflux disease/ gastric reflux	2	16OCT2020	24/15	2	No	O	NA/TC	R (30OCT2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site swelling/ SWELLING SLIGHTLY BELOW INJECTION SITE	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 1254 12541059	3^	NERV	Paraesthesia/ TINGLING SENSATION IN BOTH ARMS	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Fatigue/ Worsening of Fatigue	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		NERV	Headache/ Headache	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ worsening of fatigue	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ headache	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1254 12541065	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
		INFEC	Cellulitis/ RIGHT FIRST TOE CELLULITIS	1	10SEP2020	9/31	1	No	O	NA	R (10OCT2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1254 12541076	3^	GENRL	Injection site pain/ left arm pain at injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 1 1254 12541088	3^	GENRL	Fatigue/ FATIGUE	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
>55/ C459100 1 1254 12541095	3^	GENRL	Injection site pain/ Left upper extremity pain at injection site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
		INFEC	Tooth infection/ dental infection	1	05SEP2020	2/8	2	No	O	NA/TC	R (12SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1254 12541096	3^	GENRL	Injection site pain/ soreness at injection site in left arm	1	04SEP2020	1/5	1	Yes		NA	R (08SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
>55/ C459100 1 1254 12541097	3^	GENRL	Injection site pain/ soreness at injection site	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
>55/ C459100 1 1254 12541098	3^	GENRL	Fatigue/ fatigue	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
		INJ&P	Skin laceration/ right hand laceration	1	24SEP2020	21/22	1	No	O	NA/TC	R (15OCT2020)	N/N
		GENRL	Chills/ chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
		GENRL	Pain/ bodyache	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		GENRL	Pyrexia/ fever at 101.0F	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1254 12541103	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	06SEP2020	2/3	1	Yes		NA	R (08SEP2020)	N/N
		GASTR	Nausea/ nausea	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Dizziness/ dizziness	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
			Headache/ headache	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		GENRL	Pyrexia/ fever 102F	2	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1254 12541106	3^	GENRL	Injection site pain/ injection site soreness	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1254 12541127	3^	GENRL	Injection site pain/ INJECTION SITE TENDERNESS	1	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N
			Injection site pain/ Soreness at injection site	2	02OCT2020	1/2	2	Yes		NA/TC	R (03OCT2020)	N/N
			Pyrexia/ Fever of 100.6F	2	02OCT2020	1/2	2	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100	3^	GENRL	Fatigue/ FATIGUE	1	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1254 12541128		NERV	Headache/ HEADACHE	1	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N
>55/ C459100 1 1254 12541130	3^	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	02OCT2020	1/3	2	Yes		NA/TC	R (04OCT2020)	N/N
>55/ C459100 1 1254 12541138	3^	GENRL	Injection site pain/ INJECTION SITE PAIN	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N
		GASTR	Nausea/ nausea	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		GENRL	Chills/ chills	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
			Fatigue/ fatigue	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
			Injection site pain/ pain at injection site	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
			Pain/ bodyache	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
			Pyrexia/ fever at 100.5F	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1254 12541143	3^	GASTR	Dyspepsia/ indigestion	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
>55/ C459100 1 1254 12541146	3^	GENRL	Fatigue/ MILD FATIGUE	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
			Injection site pain/ INJECTION SITE SORENESS	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1254 12541149	3^	GENRL	Injection site pain/ pain at injection site	1	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
			Pain/ bodyache	1	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		NERV	Headache/ headache	1	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	06OCT2020	1/3	1	Yes		NA/TC	R (08OCT2020)	N/N
		GENRL	Pain/ generalized body ache	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
		NERV	Headache/ headache	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1260 12601003	3^	GENRL	Injection site pain/ soreness at injection site	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1260 12601008	3^	GENRL	Injection site pain/ soreness at injection site	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		GENRL	Chills/ chills	1	27AUG2020	2/2	2	Yes		NA	R (28AUG2020)	N/N
			Injection site pain/ soreness at injection site	1	27AUG2020	2/5	2	Yes		NA	R (31AUG2020)	N/N
		MUSC	Arthralgia/ increased aches in joints	1	27AUG2020	2/2	2	Yes		NA/TC	R (28AUG2020)	N/N
		GASTR	Diarrhoea/ diarrhea	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
		GENRL	Pain/ generalized body aches	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1260 12601019	3^	NERV	Headache/ headache	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at injection site	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N
>55/ C459100 1 1260 12601020	3^	MUSC	Myalgia/ generalized muscle aches	2	19SEP2020	2/5	2	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1260 12601025	3^	GENRL	Injection site pain/ soreness at injection site	1	31AUG2020	1/4	2	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1260 12601026	3^	GASTR	Nausea/ nausea	1	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N	
		GENRL	Fatigue/ fatigue	1	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N	
		NERV	Headache/ headache	1	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N	
		GASTR	Nausea/ nausea	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
		GENRL	Injection site pain/ soreness at injection site	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
		NERV	Headache/ headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N	
		GENRL	Fatigue/ Fatigue	1	01SEP2020	2/2	2	Yes		NA	R (02SEP2020)	N/N	
				Injection site pain/ soreness at injection site	1	01SEP2020	2/2	2	Yes		NA	R (02SEP2020)	N/N
		GENRL	Injection site pain/ soreness at the injection site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
				Pain/ generalized aches	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1260 12601027	3^	NERV	Headache/ headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N	
		GENRL	Injection site pain/ soreness at injection site	1	03SEP2020	4/1	1	Yes		NA	R (03SEP2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
			Pyrexia/ fever	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		MUSC	Myalgia/ generalized muscle aches	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ sporadic intense headache in the back of his head	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1260 12601033	3^	GENRL	Injection site pain/ left arm slightly tender at area of injection	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Injection site erythema/ redness at injection site	2	24SEP2020	4/5	1	Yes		NA	R (28SEP2020)	N/N
			Injection site pain/ soreness at injection site	2	24SEP2020	4/8	1	Yes		NA	R (01OCT2020)	N/N
			Injection site warmth/ warmth at injection site	2	24SEP2020	4/5	1	Yes		NA	R (28SEP2020)	N/N
>55/ C459100 1 1260 12601035	3^	NERV	Headache/ headache	1	01SEP2020	2/28	2	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C459100 1 1260 12601037	3^	GENRL	Injection site pain/ soreness at injection site	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1260 12601039	3^	GASTR	Small intestinal obstruction/ small bowel obstruction	2	29OCT2020	38/8	3	No	O	NA/TC/TCN	R (05NOV2020)	Y/N
		GENRL	Injection site pain/ soreness at injection site	1	01SEP2020	1/4	2	Yes		NA/TC	R (04SEP2020)	N/N
		GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	2/8	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1260 12601041	3^	GENRL	Pain/ Generalized Body Aches	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		GENRL	Fatigue/ fatigue	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site swelling/ swollen at injection site	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ headache	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
VASC	Flushing/ flushed all over	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N		
GENRL	Chills/ chills	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N		

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1260 12601046	3^	MUSC	Myalgia/ muscle aches in thighs	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Pain/ soreness around left axillary area	2	24SEP2020	3/2	1	Yes		NA	R (25SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ chills	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Injection site erythema/ redness at injection site	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1260 12601051	3^	NERV	Pyrexia/ fever 100.4	2	23SEP2020	2/2	2	Yes		NA/TC	R (24SEP2020)	N/N
		NERV	Headache/ headache	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
>55/ C459100 1 1260 12601053	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	16OCT2020	26/2	1	No	O	NA/TC	R (17OCT2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	07OCT2020	17/3	1	No	O	NA	R (09OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1260 12601056	3^	GENRL	Injection site pain/ soreness at injection site	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		GENRL	Injection site pain/ Soreness in injected arm	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		PSYCH	Sleep disorder/ Unsettled sleep	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Musculoskeletal stiffness/ Generalized body stiffness	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ Mild Headache	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 1260 12601060	3^	GENRL	Fatigue/ fatigue	1	05SEP2020	2/2	2	Yes		NA/TC	R (06SEP2020)	N/N
			Injection site pain/ left arm pain at injection site	1	05SEP2020	2/2	2	Yes		NA/TC	R (06SEP2020)	N/N
		MUSC	Back pain/ back pain	2	01OCT2020	9/4	1	No	O	NA/TC	R (04OCT2020)	N/N
		Pain in extremity/ left leg pain	2	01OCT2020	9/4	1	No	O	NA/TC	R (04OCT2020)	N/N	
>55/ C459100 1 1260 12601062	3^	GENRL	Fatigue/ fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1260 12601064	3^	GENRL	Injection site erythema/ redness at injection site	1	06SEP2020	3/4	1	Yes		NA	R (09SEP2020)	N/N
			Injection site pain/ soreness at injection site	1	06SEP2020	3/4	1	Yes		NA	R (09SEP2020)	N/N
		NERV	Migraine without aura/ intermittent migraines without aura	1	06SEP2020	3/4	2	Yes		NA	R (09SEP2020)	N/N
			Fatigue/ fatigue	1	08SEP2020	5/2	2	Yes		NA	R (09SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	25SEP2020	2/5	1	Yes		NA	R (29SEP2020)	N/N
		NERV	Injection site pain/ Soreness at injection site	2	25SEP2020	2/5	1	Yes		NA	R (29SEP2020)	N/N
			Headache/ Headache	2	25SEP2020	2/5	1	Yes		NA	R (29SEP2020)	N/N
>55/ C459100 1 1260 12601069	3^	INFEC	Appendicitis/ acute appendicitis	2	05OCT2020	12/3	2	No	O	NA/TC/TCN	R (07OCT2020)	Y/N
		VASC	Aortic aneurysm/ abdominal aortic aneurysm	2	07OCT2020	14/C	2	No	O	NA	N	N/N
>55/ C459100 1 1260 12601071	3^	GENRL	Fatigue/ fatigue	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
			Injection site pain/ soreness at injection site	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ fatigue	2	24SEP2020	1/4	2	Yes		NA	R (27SEP2020)	N/N
			Pain/ body aches	2	24SEP2020	1/3	2	Yes		NA/TC	R (26SEP2020)	N/N
		NERV	Headache/ headache	1	24SEP2020	21/1	1	No	O	NA	R (24SEP2020)	N/N
					2	24SEP2020	1/3	2	Yes		NA/TC	R (26SEP2020)
>55/ C459100 11260 12601072	3^	GENRL	Injection site pain/ soreness at the injection site	1	05SEP2020	2/1	2	Yes		NA/TC	R (05SEP2020)	N/N
		NERV	Headache/ headache	1	05SEP2020	2/1	2	Yes		NA/TC	R (05SEP2020)	N/N
			MUSC	Arthralgia/ Soreness Left Knee	1	21SEP2020	18/12	2	No	O	NA/TC	R (02OCT2020)
		GENRL	Fatigue/ fatigue	1	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
			Injection site discomfort/ arm heaviness at injection area	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		GENRL	Pain/ body aches	1	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
			Pain/ Body aches (generalized)	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
		>55/ C459100	3^	GENRL	Injection site pain/ soreness at injection site	1	08SEP2020	1/2	1	Yes	NA	R (09SEP2020)

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1260 12601079 >55/ C459100	3^	GENRL	Injection site pain/ Soreness at the injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
1 1260 12601080 >55/ C459100	3^	GENRL	Injection site pain/ soreness at injection site	1	08SEP2020	1/4	2	Yes		NA	R (11SEP2020)	N/N
1 1260 12601081		GENRL	Fatigue/ fatigue	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
>55/ C459100 1 1260 12601090	3^	GENRL	Injection site pain/ soreness at injection site	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
>55/ C459100 1 1260 12601093	3^	NERV	Headache/ headache	1	02OCT2020	24/1	1	No	O	NA/TC	R (02OCT2020)	N/N
		SKIN	Rash/ facial rash	2	04OCT2020	3/C	1	Yes		NA/TC	N	N/N
>55/ C459100 1 1260 12601095	3^	GENRL	Injection site pain/ soreness at injection site	1	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
		IMMUN	Food allergy/ allergic reaction to swedish ice cream	1	21SEP2020	13/2	2	No	O	NA/TC	R (22SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1260 12601096	3^	GASTR	Stomatitis/ mouth sores	2	30SEP2020	3/7	2	No	O	NA	R (06OCT2020)	N/N
>55/ C459100 1 1260 12601103	3^	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/5	2	Yes		NA	R (14SEP2020)	N/N
		NERV	Migraine without aura/ migraine (no aura)	1	30SEP2020	21/2	2	No	O	NA/TC	R (01OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	RS (03OCT2020)	N/N
>55/ C459100 1 1260 12601109	3^	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		GENRL	Chills/ chills	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
			Pyrexia/ fever	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/Y
		GENRL	Fatigue/ fatigue	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
			Pain/ generalized body aches	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
>55/ C459100 1 1260 12601124	3^	GENRL	Injection site pain/ soreness at injection site	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ fatigue	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ fever	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		MUSC	Myalgia/ generalized myalgia	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
			Pyrexia/ Fever (max 100.4)	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		MUSC	Myalgia/ Muscle Ache (generalized)	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
>55/ C459100 1 1260 12601131	3^	GENRL	Injection site pain/ soreness at injection site	1	19SEP2020	2/1	2	Yes		NA/TC	R (19SEP2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
>55/ C459100 1 1261 12611003	3^	GENRL	Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
>55/ C459100 1 1261 12611012	3^	GENRL	Pyrexia/ Fever	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ Diffuse myalgia	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11261 12611014	3^	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		MUSC	Muscular weakness/ Left Arm weakness	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		NERV	Dizziness/ Dizziness	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
>55/ C459100 11261 12611037	3^	GENRL	Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		IMMUN	Immunisation reaction/ Vaccine reaction	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		MUSC	Myalgia/ Diffuse Myalgia	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		NERV	Headache/ Headache	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		GASTR	Dyspepsia/ Heartburn	2	23OCT2020	29/C	2	No	O	NA/TC	N	N/N
		METAB	Hyperlipidaemia/ Hyperlipidemia	2	24OCT2020	30/C	2	No	O	NA/TC	N	N/N
		GASTR	Aphthous ulcer/ Canker sore	2	25OCT2020	31/4	2	No	O	NA/TC	R (28OCT2020)	N/N
>55/ C459100 11261 12611055	3^	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1261 12611068	3^	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100 1 1261 12611068	3^	MUSC	Myalgia/ Myalgia - lower back and neck	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
>55/ C459100 1 1261 12611069	3^	GENRL	Chills/ CHILLS - ADVERSE REACTION TO VACCINATION 2	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1261 12611073	3^	MUSC	Pyrexia/ FEVER SECONDARY TO VACCINATION 2	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1261 12611073	3^	GENRL	Myalgia/ MYALGIA - ADVERSE REACTION TO VACCINATION 2	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
>55/ C459100 1 1261 12611073	3^	GENRL	Pyrexia/ Fever	1	13SEP2020	3/3	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1261 12611076	3^	GENRL	Pyrexia/ fever	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
>55/ C459100 1 1261 12611076	3^	GENRL	Injection site pain/ Left arm injection site pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
>55/ C459100	3^	GENRL	Injection site pain/ Injection site arm tenderness/pain	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1261 12611081		CARD	Coronary artery disease/ Worsening coronary artery disease	2	28OCT2020	24/C	2	No	O	NA	N	N/N
>55/ C459100 1 1264 12641031	3^	MUSC	Arthralgia/ Shoulder pain	2	09OCT2020	27/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1264 12641038	3^	GENRL	Feeling hot/ Warm sensation in the body (no fever when measured)	1	26AUG2020	3/2	2	Yes		NA/TC	R (27AUG2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1264 12641057	3^	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
>55/ C459100 1 1264 12641097	3^	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N
			Pyrexia/ Fever	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	21SEP2020	1/4	2	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C459100	3^	GASTR	Diarrhoea/ diarrhea	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1264 12641117		METAB	Hyperglycaemia/ Hyperglycemia	2	27SEP2020	4/8	1	No	O	NA	R (04OCT2020)	N/N
>55/ C459100 1 1264 12641121	3^	GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
			Malaise/ Malaise	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1264 12641133	3^	GASTR	Nausea/ Nausea	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
		NERV	Headache/ Headache	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100 1 1264 12641149	3^	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 1 1264 12641155	3^	GENRL	Injection site pain/ Pain at injection site	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
		RESP	Dyspnoea exertional/ Shortness of breath with minor exertion	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1264 12641180	3^	GENRL	Injection site pain/ Injection site pain	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
		NERV	Headache/ Headache	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
			Lethargy/ Lethargy	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1264 12641195	3^	GASTR	Cheilitis/ Cheilitis	1	07OCT2020	16/34	2	Yes		NA/TC	R (09NOV2020)	N/N
			Dry mouth/ Dry mouth	1	07OCT2020	16/C	2	Yes		NA	N	N/N
		NERV	Dysgeusia/ Dysgeusia	1	07OCT2020	16/38	1	Yes		NA	R (13NOV2020)	N/N
			Parosmia/ Hyperosmia	1	07OCT2020	16/38	1	Yes		NA	R (13NOV2020)	N/N
		SKIN	Eczema/ Worsening eczema	1	07OCT2020	16/C	2	Yes		NA	N	N/N
			Pruritus/ Pruritus	1	07OCT2020	16/C	2	Yes		NA/TCN	N	N/N
			Rash maculo-papular/ Rash maculo-papular	1	07OCT2020	16/C	1	Yes		NA/TCN	N	N/N
>55/ C459100 1 1264 12641198	3^	GENRL	Chills/ Chills	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1265 12651019	3^	SURG	Injection site pain/ Injection site pain	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
			Dental implantation/ Dental implant	1	17SEP2020	21/1	1	No	O	NA/TCN	R (17SEP2020)	N/N
>55/ C459100 1 1265 12651026	3^	GENRL	Pyrexia/ Fever	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		GASTR	Diverticulum/ Diverticulosis	1	16SEP2020	17/1	1	No	O	NA	R (16SEP2020)	N/N
>55/ C459100 1 1265 12651056	3^	GENRL	Haemorrhoids/ Internal hemorrhoids	1	16SEP2020	17/1	1	No	O	NA	R (16SEP2020)	N/N
			NEOPL	Adenoma benign/ Tubular adenoma	1	16SEP2020	17/1	1	No	O	NA/TCN	R (16SEP2020)
>55/ C459100 1 1265 12651068	3^	GENRL	Asthenia/ Sensation of generalized weakness	2	26SEP2020	3/2	1	Yes		NA	R (27SEP2020)	N/N
				Fatigue/ Fatigue	2	26SEP2020	3/2	1	Yes		NA	R (27SEP2020)
>55/ C459100 1 1265 12651068	3^	GENRL	Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
>55/ C459100	3^	MUSC	Neck pain/ NECK PAIN	1	22SEP2020	14/C	2	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1265 12651080			Pain in extremity/ RIGHT ARM PAIN	1	22SEP2020	14/C	2	No	O	NA	N	N/N
>55/ C459100 1 1265 12651107	3^	EAR	Cerumen impaction/ Bilateral cerumen impaction	2	07OCT2020	2/1	1	No	O	NA/TCN	R (07OCT2020)	N/N
		MUSC	Musculoskeletal discomfort/ Right neck fullness	2	07OCT2020	2/1	1	No	O	NA	R (07OCT2020)	N/N
>55/ C459100 1 1265 12651113	3^	GENRL	Injection site discomfort/ Injection site discomfort	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1265 12651118	3^	GENRL	Fatigue/ FATIGUE	2	07OCT2020	2/12	1	No	O	NA	R (18OCT2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	07OCT2020	2/12	1	No	O	NA	R (18OCT2020)	N/N
>55/ C459100 1 1265 12651119	3^	METAB	Type 2 diabetes mellitus/ Worsening of type 2 diabetes mellitus	1	28SEP2020	14/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C459100 1 1265 12651120	3^	MUSC	Myalgia/ Muscle pain	1	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1265 12651122	3 [^]	GENRL	Fatigue/ Fatigue	1	17SEP2020	2/3	1	No	O	NA	R (19SEP2020)	N/N
		EYE	Cataract/ Worsening of cataracts, bilateral	2	08OCT2020	2/C	2	No	O	NA	N	N/N
			Dry eye/ Bilateral dry eye syndrome	2	08OCT2020	2/C	1	No	O	NA	N	N/N
>55/ C459100 1 1265 12651137	3 [^]	GASTR	Abdominal discomfort/ Abdominal pressure sensation	1	18SEP2020	2/8	1	No	O	NA	R (25SEP2020)	N/N
		GENRL	Pain/ Minor body aches	1	20SEP2020	4/1	1	No	O	NA	R (20SEP2020)	N/N
>55/ C459100 1 1265 12651150	3 ^{^†}	EYE	Vitreous detachment/ Acute posterior vitreous detachment (left eye)	1	29SEP2020	9/C	2	No	O	NA	RG	N/N
		RESP	Rhinorrhoea/ Rhinorrhea	2	06NOV2020	26/4	1	No	O	NA	R (09NOV2020)	N/N
>55/ C459100 1 1265 12651152	3 [^]	INFEC	Oral herpes/ Cold sores	1	08OCT2020	18/33	1	Yes		NA/TC	R (09NOV2020)	N/N
>55/ C459100 1 1265 12651158	3 [^]	GENRL	Fatigue/ Mild fatigue	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1265 12651171	3^	GENRL	Injection site discomfort/ Injection site discomfort	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ Injection site pain with radiation to elbow	2	16OCT2020	2/C	1	Yes		NA	RG	N/N
		MUSC	Tendonitis/ Left tendonitis	2	24OCT2020	10/1	1	No	O	NA	R (24OCT2020)	N/N
		INFEC	Orchitis/ Right orchitis	2	25OCT2020	11/6	1	No	O	NA/TC	R (30OCT2020)	N/N
>55/ C459100 1 1265 12651184	3^	GENRL	Pyrexia/ FEVER	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
>55/ C459100 1 1269 12691009	3^	SKIN	Pruritus/ lower back itching	2	15SEP2020	6/2	1	No	O	NA/TC	R (16SEP2020)	N/N
>55/ C459100 1 1269 12691019	3^	GENRL	Chills/ chills	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
			Fatigue/ fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
			Pyrexia/ fever	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Arthralgia/ joint aches	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
			Myalgia/ muscle aches	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		NERV	Headache/ headache	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
>55/ C459100 1 1269 12691028	3^	MUSC	Arthralgia/ Joint pains	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
			Myalgia/ muscle pains	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		NERV	Headache/ headaches	2	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
>55/ C459100 1 1269 12691035	3^	GENRL	Pyrexia/ fever	2	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N
		MUSC	Pain in extremity/ left arm soreness	2	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N
>55/ C459100 1 1269 12691036	3^	GASTR	Diarrhoea/ diarrhea	1	26AUG2020	5/1	1	No	O	NA	R (26AUG2020)	N/N
>55/ C459100 1 1269 12691043	3^	GASTR	Diarrhoea/ worsening of diarrhea*		24AUG2020	1/1	1	No	O	NA	R (24AUG2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1269 12691046	3^	MUSC	Muscle spasms/ worsening of leg cramps	2	20SEP2020	5/1	1	No	O	NA	R (20SEP2020)	N/N
		GASTR	Diarrhoea/ diarrhea	2	11OCT2020	26/1	1	No	O	NA/TC	R (11OCT2020)	N/N
>55/ C459100 1 1269 12691053	3^	GENRL	Chills/ chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
			Fatigue/ fatigue	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
			Pyrexia/ fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
>55/ C459100 1 1269 12691066	3^	GENRL	Chills/ chills	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
			Injection site pain/ soreness at injection site	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ fever	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		MUSC	Joint stiffness/ stiff joints	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
			Myalgia/ muscle aches	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1269 12691071	3^	NERV	Headache/ headache	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		RESP	Upper respiratory tract congestion/ mild head congestion	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ chills	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
			Fatigue/ fatigue	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		GASTR	Abdominal pain upper/ stomach cramps	2	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
>55/ C459100 1 1269 12691082	3^	RENAL	Micturition urgency/ increased urge to urinate	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		NERV	Headache/ headaches	2	22SEP2020	5/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		MUSC	Myalgia/ muscle aches	2	23SEP2020	6/2	1	Yes		NA/TC	R (24SEP2020)	N/N
>55/ C459100 1 1269 12691090	3^	GENRL	Injection site pain/ soreness at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
			Pyrexia/ fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1269 12691109	3^	MUSC	Myalgia/ muscle aches	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Headache/ headache	2	01OCT2020	10/2	1	No	O	NA	R (02OCT2020)	N/N
		RESP	Oropharyngeal pain/ sore throat	1	15SEP2020	13/3	1	No	O	NA	R (17SEP2020)	N/N
		SKIN	Pruritus/ lower back itching	1	15SEP2020	13/2	1	No	O	NA/TC	R (16SEP2020)	N/N
>55/ C459100 1 1270 12701002	3^	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
>55/ C459100 1 1270 12701006	3^	GENRL	Pyrexia/ Fever	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		NERV	Headache/ Headache	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	2	17SEP2020	3/1	1	Yes		NA	R (17SEP2020)	N/N
		SKIN	Dermatitis contact/ Poison Oak Rash	1	01SEP2020	7/30	2	No	O	NA	R (30SEP2020)	N/N
		GENRL	Chills/ Chills	1	27AUG2020	2/7	1	Yes		NA	R (02SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1270 12701019	3^	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
			Chills/ Chills	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
			Pyrexia/ Fever	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
			Chills/ Chills	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
			Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1270 12701024	3^	GENRL	Injection site pain/ Pain at injection site	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
			Chills/ Chills	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
>55/ C459100 1 1270 12701028	3^	NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
>55/ C459100 1 1270 12701032	3^	GASTR	Diverticulum intestinal/ Diverticulosis of colon	1	17SEP2020	18/C	1	No	O	NA	N	N/N
			Haemorrhoids/ Internal Hemorrhoids	1	17SEP2020	18/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NEOPL	Colon adenoma/ Adenomatous polyps of colon	1	17SEP2020	18/C	1	No	O	NA	N	N/N
>55/ C459100 1 1270 12701036	3^	GENRL	Injection site pain/ Pain at Injection Site	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
>55/ C459100 1 1270 12701038	3^	EYE	Eye irritation/ Burning Eyes	1	02SEP2020	2/2	1	No	O	NA	R (03SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	1	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N
		RESP	Throat irritation/ Scratchy throat	1	02SEP2020	2/2	1	No	O	NA	R (03SEP2020)	N/N
>55/ C459100 1 1270 12701043	3^	GENRL	Injection site pain/ Pain at injection site	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
		GENRL	Chills/ CHILLS	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		MUSC	Bone pain/ LEFT THUMB METACARPPOPHALANGEA L PAIN	1	16SEP2020	16/C	2	No	O	NA	N	N/N
		GENRL	Chills/ Chills	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
			Injection site pain/ Pain at injection site	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1270 12701047	3^	MUSC	Myalgia/ MUSCEL ACHES	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	23SEP2020	2/2	2	Yes		NA/TC	R (24SEP2020)	N/N
		GASTR	Nausea/ Nausea	1	02SEP2020	1/1	2	Yes		NA/TCN	R (02SEP2020)	N/N
		NERV	Headache/ Headache	1	02SEP2020	1/1	3	Yes		NA/TC/TCN	R (02SEP2020)	N/N
		SKIN	Actinic keratosis/ Actinic Keratosis	2	05OCT2020	13/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 1270 12701050	3^	SKIN	Stasis dermatitis/ Chronic Venous Stasis Dermatitis	2	05OCT2020	13/C	1	No	O	NA/TC	N	N/N
		GENRL	Injection site pain/ Left arm pain at injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
>55/ C459100 1 1270 12701054	3^	NERV	Headache/ Headache	1	24SEP2020	23/1	1	No	O	NA	R (24SEP2020)	N/N
		GENRL	Injection site pain/ left arm pain at injection site	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
>55/ C459100 1 1270 12701055	3^	GENRL	Injection site pain/ Pain at Injection Site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ Pain at injection site	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
>55/ C459100 1 1270 12701057	3^	RESP	Pulmonary embolism/ Pulmonary embolism	1	23SEP2020	21/C	3	No	O	P/TC	RG	Y/N
>55/ C459100 1 1270 12701059	3^	GASTR	Nausea/ Nausea	1	09SEP2020	7/2	1	No	O	NA	R (10SEP2020)	N/N
>55/ C459100 1 1270 12701063	3^	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		MUSC	Arthralgia/ Joint pain	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		NERV	Headache/ Headache	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 1270 12701067	3^	MUSC	Pain in extremity/ Left Foot Pain	2	02OCT2020	8/C	1	No	O	NA/TC/TCN	RG	N/N
		INV	High density lipoprotein increased/ Increased High Density Lipoproteins	2	03OCT2020	9/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1270 12701070	3^	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1270 12701081	3^	SKIN	Skin lesion/ Skin Lesions Buttocks	2	08OCT2020	10/9	1	No	O	NA	R (16OCT2020)	N/N
>55/ C459100 1 1270 12701093	3^	NEOPL	Basal cell carcinoma/ Right Lateral Lower Eyelid Basal Cell Carcinoma, Nodular Type	1	28SEP2020	18/C	2	No	O	NA	N	N/N
>55/ C459100 1 1270 12701094	3^	GENRL	Injection site pain/ Injection site pain	1	11SEP2020	1/4	2	Yes		NA/TC	R (14SEP2020)	N/N
		MUSC	Myalgia/ Muscle aches	1	12SEP2020	2/3	1	Yes		NA/TC	R (14SEP2020)	N/N
>55/ C459100 1 1270 12701095	3^	INV	Platelet count increased/ Elevated Platlett	2	26OCT2020	25/C	1	No	O	NA	N	N/N
		INV	Blood thyroid stimulating hormone increased/ Elevated Thyroid Stimulating Hormone	2	27OCT2020	26/C	1	No	O	NA	N	N/N
			Low density lipoprotein increased/ Elevated low-density lipoprotein	2	27OCT2020	26/C	1	No	O	NA	N	N/N
>55/ C459100 1 1270 12701101	3^	GASTR	Abdominal pain upper/ Epigastric Abdominal Pain	2	19OCT2020	15/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1270 12701102	3^	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/5	2	Yes		NA/TC	R (09OCT2020)	N/N
		MUSC	Muscle fatigue/ Muscle Fatigue	2	05OCT2020	1/4	2	Yes		NA	R (08OCT2020)	N/N
			Myalgia/ Muscle Aches	2	05OCT2020	1/2	2	Yes		NA/TC	R (06OCT2020)	N/N
>55/ C459100 1 1270 12701103	3^	GENRL	Injection site pain/ Injection site pain	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1270 12701104	3^	NERV	Dizziness/ Dizziness	2	05NOV2020	32/1	2	No	O	NA	R (05NOV2020)	N/N
		SKIN	Hyperhidrosis/ Diaphoretic	2	05NOV2020	32/1	2	No	O	NA	R (05NOV2020)	N/N
		VASC	Pallor/ Pale	2	05NOV2020	32/1	2	No	O	NA	R (05NOV2020)	N/N
>55/ C459100 1 1270 12701106	3^	GENRL	Injection site pain/ Injection site pain	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
>55/ C459100 1 1270 12701111	3^	GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1270 12701113	3^	RENAL	Dysuria/ Dysuria	2	11OCT2020	3/6	1	No	O	NA/TC	R (16OCT2020)	N/N
>55/ C459100 1 1270 12701114	3^	GENRL	Fatigue/ Fatigue	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
			Injection site pain/ Injection site pain	1	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
		MUSC	Myalgia/ Muscle Aches	1	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
>55/ C459100 1 1270 12701127	3^	GASTR	Nausea/ Nausea	1	19SEP2020	3/1	2	Yes		NA	R (19SEP2020)	N/N
			Vomiting/ Vomiting	1	19SEP2020	3/1	1	Yes		NA	R (19SEP2020)	N/N
		GENRL	Chills/ Chills	1	19SEP2020	3/1	1	Yes		NA	R (19SEP2020)	N/N
			Pyrexia/ Fever (Highest 101.5°F)	1	19SEP2020	3/1	2	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ Headache	1	19SEP2020	3/1	1	Yes		NA	R (19SEP2020)	N/N
		REPRO	Breast pain/ Right Mastodynia	1	20SEP2020	4/7	2	No	O	NA	R (26SEP2020)	N/N
>55/ C459100	3^	VASC	Hypertension/ Worsening Hypertension	2	28OCT2020	20/C	1	No	O	NA/TC	N	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1270 12701130 >55/ C459100	3^	GASTR	Diarrhoea/ Diarrhea, once	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
1 1270 12701138 >55/ C459100	3^	GENRL	Injection site pain/ Injection site arm pain	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
1 1270 12701140		GASTR	Diarrhoea/ Diarrhea	1	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
			Nausea/ Nausea	1	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
		GENRL	Chills/ Chills	1	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
		NERV	Headache/ Headache	1	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
>55/ C459100 1 4444 44441001	3^	GENRL	Asthenia/ asthenia	2	12OCT2020	1/3	2	Yes		NA	R (14OCT2020)	N/N
		MUSC	Myalgia/ left arm muscle pain	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 4444 44441002	3^	INFEC	Tooth infection/ Odontogenic infection	2	22OCT2020	11/6	1	No	O	NA/TC	R (27OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 4444 44441006	3^	GENRL	Pyrexia/ fever	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
>55/ C459100 1 4444 44441010	3^	GENRL	Asthenia/ asthenia	1	21SEP2020	1/8	1	Yes		NA	R (28SEP2020)	N/N
		MUSC	Pain in extremity/ pain in left upper limb	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
		MUSC	Myalgia/ right arm muscle pain	2	12OCT2020	1/2	1	Yes		NA/TC/TCN	R (13OCT2020)	N/N
>55/ C459100 1 4444 44441041	3^	INJ&P	Thermal burn/ Burn on right forearm. Classification AB	2	05NOV2020	24/C	2	No	O	NA/TCN	RG	N/N
>55/ C459100 1 4444 44441042	3^	METAB	Dyslipidaemia/ Dyslipidemia	1	22SEP2020	2/8	1	No	O	NA/TC/TCN	R (29SEP2020)	N/N
		MUSC	Osteitis/ Right hip trochanteritis worsening	1	09OCT2020	19/C	2	No	O	NA/TC/TCN	RG	N/N
		CARD	Ventricular extrasystoles/ Frequent ventricular extrasystoles	2	13OCT2020	2/1	1	No	O	NA/TC/TCN	R (13OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 4444 44441050	3^	INFEC	Urinary tract infection/ Urinary infection	1	01OCT2020	11/10	2	No	O	NA/TC/TCN	R (10OCT2020)	N/N
>55/ C459100 1 4444 44441051	3^	GENRL	Injection site pain/ Injection site pain in right arm.	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 4444 44441053	3^	GASTR	Abdominal pain/ Abdominal pain	2	13OCT2020	2/2	2	Yes		NA	R (14OCT2020)	N/N
			Diarrhoea/ Diarrhea	2	13OCT2020	2/2	2	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 4444 44441058	3^	GENRL	Injection site pain/ Pain on injection site	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		GENRL	Asthenia/ asthenia	2	13OCT2020	1/4	1	Yes		NA/TC	R (16OCT2020)	N/N
		RESP	Nasal congestion/ Congestion nasal	2	13OCT2020	1/4	1	Yes		NA/TC	R (16OCT2020)	N/N
>55/ C459100 1 4444 44441059	3^	GASTR	Abdominal distension/ abdominal distention	1	22SEP2020	2/7	2	No	O	NA/TC	R (28SEP2020)	N/N
			Proctalgia/ Pain in anus	1	22SEP2020	2/7	2	No	O	NA/TC	R (28SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 4444 44441074	3^	GENRL	Asthenia/ asthenia	1	21SEP2020	1/7	2	Yes		NA	R (27SEP2020)	N/N
		INFEC	Conjunctivitis/ conjunctivitis of the left eye	2	12OCT2020	1/11	1	No	O	NA/TC	R (22OCT2020)	N/N
		INFEC	Conjunctivitis/ Recurrent conjunctivitis	2	26OCT2020	15/7	1	No	O	NA/TC	R (01NOV2020)	N/N
>55/ C459100 1 4444 44441078	3^	RENAL	Dysuria/ burning when urinating	1	10OCT2020	20/2	1	No	O	NA	R (11OCT2020)	N/N
>55/ C459100 1 4444 44441080	3^	VASC	Hypertension/ Arterial Hypertension Exacerbation	1	24SEP2020	4/2	1	No	CD	NA	R (25SEP2020)	N/N
>55/ C459100 1 4444 44441091	3^	INJ&P	Fall/ fall from own height	2	11NOV2020	31/1	2	No	O	NA/TCN	R (11NOV2020)	N/N
			Ligament sprain/ right ankle sprain	2	11NOV2020	31/C	2	No	O	NA/TC/TCN	RG	N/N
>55/ C459100 1 4444 44441097	3^	RESP	Bronchospasm/ bronchospasm	1	28SEP2020	8/1	1	No	O	NA/TC	R (28SEP2020)	N/N
>55/ C459100 1 4444 44441107	3^	EYE	Conjunctivitis allergic/ allergic conjunctivitis	1	29SEP2020	9/2	1	No	O	NA/TC	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 4444 44441112	3^	SKIN	Erythema/ redness of both upper limbs	1	25SEP2020	5/8	1	No	O	NA/TC	R (02OCT2020)	N/N
		GASTR	Abdominal pain upper/ Epigastralgia	2	02NOV2020	21/1	1	No	O	NA/TC	R (02NOV2020)	N/N
>55/ C459100 1 4444 44441114	3^	NERV	Headache/ Short-term headache	1	05OCT2020	15/2	1	No	O	NA	R (06OCT2020)	N/N
		REPRO	Vulvovaginal pruritus/ vaginal itching	2	05NOV2020	25/4	1	No	O	NA/TC	R (08NOV2020)	N/N
>55/ C459100 1 4444 44441116	3^	INFECTION	Tooth infection/ Tooth infection	2	04NOV2020	24/5	1	No	O	NA/TC/TCN	R (08NOV2020)	N/N
>55/ C459100 1 4444 44441127	3^	GENRL	Asthenia/ Asthenia	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 4444 44441130	3^	SKIN	Blister/ blisters on the back of both hands	1	23SEP2020	3/12	1	No	O	NA/TC	R (04OCT2020)	N/N
			Rash/ Rash on the back of both hands	1	23SEP2020	3/12	1	No	O	NA/TC	R (04OCT2020)	N/N
		SKIN	Skin lesion/ erythematous lesions on both forearms	1	02OCT2020	12/3	1	No	O	NA/TC	R (04OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INV	Body temperature increased/ Body temperature increased	2	14OCT2020	2/1	1	Yes		NA/TC/TCN	R (14OCT2020)	N/N
>55/ C459100 1 4444 44441136	3^	MUSC	Back pain/ Low back pain	1	01OCT2020	11/1	1	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 4444 44441140	3^	RESP	Dysphonia/ Dysphonia	1	02OCT2020	12/6	1	No	O	NA	R (07OCT2020)	N/N
>55/ C459100 1 4444 44441141	3^	VASC	Hypertension/ Arterial hypertension	2	23OCT2020	12/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 4444 44441148	3^	GASTR	Gastritis/ Acute gastritis	1	22SEP2020	2/18	1	No	O	NA/TC	R (09OCT2020)	N/N
>55/ C459100 1 4444 44441158	3^	NERV	Intention tremor/ Intentional fine tremor of the left hand lasting one to two minutes	1	01OCT2020	11/12	1	No	O	NA	R (12OCT2020)	N/N
		GASTR	Tooth disorder/ dental mobility	1	08OCT2020	18/2	1	No	O	NA/TC/TCN	R (09OCT2020)	N/N
>55/ C459100 1 4444 44441165	3^	INFEC	Tooth infection/ Left lower first molar infection	2	14OCT2020	2/27	1	No	O	NA/TC	R (09NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INFEC	Herpes zoster/ Herpes zoster in the right anterior thoracic region	2	21OCT2020	9/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 4444 44441168	3^	GENRL	Asthenia/ Asthenia	2	14OCT2020	2/5	1	Yes		NA	R (18OCT2020)	N/N
			Injection site pain/ Injection site pain	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 4444 44441178	3^	GENRL	Asthenia/ Asthenia	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 4444 44441196	3^	GASTR	Abdominal pain/ nonspecific abdominal pain	1	09OCT2020	19/5	1	No	O	NA/TC	R (13OCT2020)	N/N
>55/ C459100 1 4444 44441215	3^	MUSC	Myalgia/ Generalized myalgia	1	22SEP2020	2/6	3	Yes		NA/TC	R (27SEP2020)	N/N
>55/ C459100 1 4444 44441221	3^	GENRL	Injection site pain/ Injection site pain	2	14OCT2020	1/5	2	Yes		NA/TC	R (18OCT2020)	N/N
		GENRL	Asthenia/ Asthenia	2	16OCT2020	3/3	1	Yes		NA	R (18OCT2020)	N/N
>55/ C459100	3^	MUSC	Myalgia/ Myalgia	2	12OCT2020	1/2	2	Yes		NA	R (13OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 4444 44441227		GENRL	Pyrexia/ fever	2	13OCT2020	2/1	2	Yes		NA/TC	R (13OCT2020)	N/N
>55/ C459100 1 4444 44441229	3^	METAB	Type 2 diabetes mellitus/ Type 2 diabetes	1	30SEP2020	10/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C459100 1 4444 44441231	3^	GENRL	Asthenia/ asthenia	2	13OCT2020	2/5	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 4444 44441235	3^	REPRO	Benign prostatic hyperplasia/ exacerbation of benign prostatic hyperplasia	2	28OCT2020	16/17	1	No	O	NA/TC	R (13NOV2020)	N/N
>55/ C459100 1 4444 44441239	3^	INJ&P	Tooth fracture/ Tooth breakage	2	05NOV2020	25/1	1	No	O	NA/TC/TCN	R (05NOV2020)	N/N
		SURG	Tooth extraction/ Tooth extraction	2	05NOV2020	25/1	1	No	O	NA/TC	R (05NOV2020)	N/N
>55/ C459100 1 4444 44441242	3^	NERV	Paraesthesia/ Paraesthesia	1	23SEP2020	3/C	1	No	O	NA	N	N/N
>55/ C459100	3^	GENRL	Pyrexia/ Fever	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 4444 44441274 >55/ C459100 1 4444 44441287	3^	MUSC	Back pain/ Low back pain	1	26SEP2020	5/6	1	No	O	NA/TC	R (01OCT2020)	N/N
		GENRL	Asthenia/ Asthenia	2	17OCT2020	5/1	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 4444 44441303	3^	GASTR	Dental caries/ dental caries	1	29SEP2020	8/5	1	No	O	NA/TC	R (03OCT2020)	N/N
>55/ C459100 1 4444 44441309	3^	INFEC	Cystitis/ Lower urinary tract infection (cystitis)	1	28SEP2020	7/13	2	No	O	NA/TC	R (10OCT2020)	N/N
		NERV	Headache/ Headache	1	28SEP2020	7/3	1	No	O	NA/TC	R (30SEP2020)	N/N
		NERV	Headache/ Headache	2	20OCT2020	9/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 4444 44441313	3^	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
>55/ C459100 1 4444 44441318	3^	NERV	Headache/ Headache	1	24SEP2020	3/2	1	Yes		NA/TC	R (25SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 4444 44441322	3^	INJ&P	Ligament sprain/ right ankle sprain	2	13OCT2020	2/29	1	No	O	NA/TCN	R (10NOV2020)	N/N
>55/ C459100 1 4444 44441331	3^	GENRL	Injection site pain/ injection site pain	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		GENRL	Pyrexia/ fever (38.5 C)	1	12OCT2020	21/3	1	Yes		NA/TC	R (14OCT2020)	N/N
		MUSC	Myalgia/ generalized myalgia	1	12OCT2020	21/3	1	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C459100 1 4444 44441338	3^	GENRL	Asthenia/ Asthenia	2	13OCT2020	1/4	1	Yes		NA	R (16OCT2020)	N/N
			Injection site pain/ Injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		NERV	Headache/ Headache	2	13OCT2020	1/4	1	Yes		NA/TC	R (16OCT2020)	N/N
		HEPAT	Cholelithiasis/ Gallstones	2	10NOV2020	29/C	1	No	O	NA	N	N/N
		INJ&P	Procedural hypotension/ Hypotension during blood sample collection	2	12NOV2020	31/1	1	No	O	NA	R (12NOV2020)	N/N
>55/ C459100 1 4444 44441343	3^	MUSC	Pain in extremity/ pain in left upper limb up to the middle finger of the hand.	1	22SEP2020	1/9	1	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 4444 44441367	3^	GENRL	Asthenia/ Asthenia	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		MUSC	Myalgia/ Generalized myalgias	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
>55/ C459100 1 4444 44441369	3^	GENRL	Discomfort/ General discomfort	1	12OCT2020	21/3	1	No	O	NA	R (14OCT2020)	N/N
>55/ C459100 1 4444 44441370	3^	RESP	Rhinitis allergic/ worsening allergic rhinitis	1	02OCT2020	11/8	1	No	O	NA	R (09OCT2020)	N/N
>55/ C459100 1 4444 44441372	3^	INFEC	Tooth infection/ Dental infection	1	22SEP2020	1/15	1	No	O	NA/TC/TCN	R (06OCT2020)	N/N
		NERV	Headache/ Headache	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	13OCT2020	2/2	2	Yes		NA	R (14OCT2020)	N/N
		METAB	Vitamin D deficiency/ Vitamin D deficiency	2	19OCT2020	8/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 1 4444 44441375	3^	MUSC	Back pain/ WORSENER LOW BACK PAIN	2	15OCT2020	3/1	2	No	O	NA/TC	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 4444 44441422	3^	MUSC	Pain in extremity/ Pain in left heel	1	28SEP2020	7/1	1	No	O	NA/TC	R (28SEP2020)	N/N
>55/ C459100 1 4444 44441441	3^	INFEC	Abscess limb/ Abscessed lesion in the middle finger of the right hand	1	05OCT2020	14/11	1	No	O	NA/TC/TCN	R (15OCT2020)	N/N
>55/ C459100 1 4444 44441449	3^	SKIN	Hand dermatitis/ dermatitis on both hands	1	28SEP2020	7/4	1	No	O	NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 4444 44441468	3^	INFEC	Erysipelas/ erysipelas on left leg	1	07OCT2020	16/21	1	No	O	NA/TC/TCN	R (27OCT2020)	N/N
>55/ C459100 1 4444 44441473	3^	HEPAT	Biliary colic/ Biliary colic	2	02NOV2020	21/2	1	No	O	NA/TC/TCN	R (03NOV2020)	N/N
>55/ C459100 1 4444 44441513	3^	REPRO	Breast pain/ Mastalgia	1	05OCT2020	14/1	1	No	O	NA	R (05OCT2020)	N/N
>55/ C459100 1 4444 44441533	3^	GASTR	Abdominal pain upper/ Epigastralgia	1	05OCT2020	14/1	1	No	O	NA/TC/TCN	R (05OCT2020)	N/N
>55/ C459100	3^	INFEC	Tooth infection/ Dental infection	2	05NOV2020	23/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 4444 44441548 >55/ C459100 1 4444 44441551	3^	NERV	Headache/ Frontal headache	1	13OCT2020	21/1	1	No	O	NA/TC	R (13OCT2020)	N/N
		NERV	Headache/ frontal headache	2	21OCT2020	8/2	1	No	O	NA/TC	R (22OCT2020)	N/N
>55/ C459100 1 4444 44441588	3^	VASC	Hypertension/ Isolated arterial hypertension record	1	01OCT2020	9/1	1	No	O	NA	RS (01OCT2020)	N/N
>55/ C459100 1 4444 44441607	3^	INFEC	Erysipelas/ Erysipelas in left leg	2	02NOV2020	20/5	1	No	O	NA/TC	R (06NOV2020)	N/N
		MUSC	Back pain/ Low back pain	2	09NOV2020	27/4	1	No	O	NA/TC	R (12NOV2020)	N/N
>55/ C459100 1 4444 44441613	3^	EAR	Vertigo/ Worsening of Peripheral Vertiginous Syndrome	1	12OCT2020	20/3	2	No	O	NA/TC/TCN	R (14OCT2020)	N/N
		MUSC	Myalgia/ myalgia	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 4444 44441625	3^	GASTR	Haemorrhoids/ Hemorrhoids	1	27SEP2020	5/12	1	No	O	NA/TC	R (08OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 4444 44441626	3^	MUSC	Myalgia/ GENERALIZED MYALGY	1	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 4444 44441645	3^	GENRL	Injection site pain/ pain at the injection site in the left arm	1	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
>55/ C459100 1 4444 44441646	3^	INFEC	Urinary tract infection/ Lower urinary infection	2	22OCT2020	9/8	1	No	O	NA/TC	R (29OCT2020)	N/N
>55/ C459100 1 4444 44441656	3^	MUSC	Pain in extremity/ pain on mobilization in left arm	1	25SEP2020	3/3	1	Yes		NA	R (27SEP2020)	N/N
>55/ C459100 1 4444 44441665	3^	GASTR	Diarrhoea/ Acute diarrhea	2	17OCT2020	4/3	1	No	O	NA	R (19OCT2020)	N/N
>55/ C459100 1 4444 44441666	3^	EYE	Dry eye/ Dry Eye	1	30SEP2020	8/C	1	No	O	NA/TC/TCN	RG	N/N
>55/ C459100 1 4444 44441667	3^	EYE	Eye pain/ eye pain	1	26SEP2020	4/5	2	No	O	NA/TC	R (30SEP2020)	N/N
		MUSC	Arthralgia/ arthralgias	1	26SEP2020	4/3	1	No	O	NA	R (28SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 4444 44441690	3^	SKIN	Rash/ skin rash on face and torso	1	26SEP2020	4/3	1	No	O	NA	R (28SEP2020)	N/N
		MUSC	Arthralgia/ arthralgias	1	04OCT2020	12/12	1	No	O	NA/TC/TCN	R (15OCT2020)	N/N
		MUSC	Arthralgia/ Left elbow pain	1	28SEP2020	6/3	1	No	O	NA/TCN	R (30SEP2020)	N/N
>55/ C459100 1 4444 44441703	3^	GENRL	Oedema peripheral/ edema in the left upper limb, arm, forearm and left hand	1	26SEP2020	4/4	2	No	O	NA/TC	R (29SEP2020)	N/N
>55/ C459100 1 4444 44441723	3^	MUSC	Myalgia/ Generalized myalgia	1	26SEP2020	4/4	2	Yes		NA/TC	R (29SEP2020)	N/N
		INFEC	Influenza/ Flu	1	07OCT2020	15/4	1	No	O	NA/TC	R (10OCT2020)	N/N
		MUSC	Synovial cyst/ Left hand ganglion	1	07OCT2020	15/C	1	No	O	NA/TCN	RG	N/N
		VASC	Hypotension/ arterial hypotension	1	13OCT2020	21/1	2	No	O	NA	R (13OCT2020)	N/N
		GENRL	Pyrexia/ fever	2	14OCT2020	2/2	2	Yes		NA/TC	R (15OCT2020)	N/N
		NERV	Headache/ headache	1	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 4444 44441742 >55/ C459100 1 4444 44441743	3^	MUSC	Myalgia/ Mild generalized myalgia.	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 4444 44441774	3^	GENRL	Pyrexia/ Fever	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 4444 44441803	3^	MUSC	Myalgia/ Generalized myalgia	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
>55/ C459100 1 4444 44441803	3^	GENRL	Asthenia/ asthenia	1	28SEP2020	4/4	2	Yes		NA	R (01OCT2020)	N/N
>55/ C459100 1 4444 44441811	3^	MUSC	Myalgia/ myalgia	1	28SEP2020	4/4	2	Yes		NA/TC	R (01OCT2020)	N/N
>55/ C459100 1 4444 44441811	3^	INFEC	Herpes zoster/ Worsening of herpes zoster	2	20OCT2020	5/4	1	No	O	NA/TC	R (23OCT2020)	N/N
>55/ C459100 1 4444 44441811	3^	INFEC	Tooth infection/ Odontogenic infection	2	26OCT2020	11/11	1	No	O	NA/TC/TCN	R (05NOV2020)	N/N
>55/ C459100 1 4444 44441822	3^	INJ&P	Joint dislocation/ Right hip dislocation	2	16OCT2020	1/1	3	No	O	NA/TCN	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 4444 44441831	3^	GENRL	Sensation of foreign body/ Foreign body sensation in pharynx	1	27SEP2020	3/1	2	No	O	NA	R (27SEP2020)	N/N
		SKIN	Hyperhidrosis/ Sweating	2	16OCT2020	1/1	1	Yes		NA	R (16OCT2020)	N/Y
		GASTR	Abdominal pain upper/ Pain in epigastrium	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
			Vomiting/ Vomiting	2	17OCT2020	2/1	2	Yes		NA	R (17OCT2020)	N/N
		GENRL	Pyrexia/ fever	2	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N
		NERV	Hypersomnia/ Hypersomnia	2	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N
>55/ C459100 1 4444 44441865	3^	NERV	Parosmia/ Hyperosmia	2	25OCT2020	11/17	1	No	O	NA	R (10NOV2020)	N/N
>55/ C459100 1 4444 44441867	3^	GASTR	Diarrhoea/ Diarrhea	2	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 4444 44441890	3^	GENRL	Pyrexia/ Fever	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 4444 44441894	3^	EAR	Vertigo/ Worsening of vertiginous syndrome	1	28SEP2020	4/17	2	No	O	NA/TC	R (14OCT2020)	N/N
>55/ C459100 1 4444 44441905	3^	GASTR	Diarrhoea/ acute diarrhea	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
		NERV	Headache/ headache	2	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 4444 44441922	3^	RESP	Rhinitis allergic/ allergic rhinitis.	1	26SEP2020	2/2	1	No	O	NA/TC	R (27SEP2020)	N/N
>55/ C459100 1 4444 44441941	3^	INFEC	Vulvovaginal mycotic infection/ Fungal vulvovaginitis	1	04OCT2020	10/1	1	No	O	NA/TC	R (04OCT2020)	N/N
		REPRO	Vaginal haemorrhage/ Vaginal hemorrhage	1	04OCT2020	10/1	1	No	O	NA/TC	R (04OCT2020)	N/N
>55/ C459100 1 4444 44442012	3^	NERV	Facial paralysis/ Left peripheral facial palsy	1	31OCT2020	37/C	2	No	O	NA/TC/TCN	N	N/N
>55/ C459100 1 4444 44442063	3^	MUSC	Pain in extremity/ Left arm pain	1	13OCT2020	17/5	1	No	O	NA	R (17OCT2020)	N/N
>55/ C459100	3^	GASTR	Nausea/ nausea	1	12OCT2020	16/1	1	No	O	NA/TC	R (12OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 4444 44442096												
>55/ C459100 1 4444 44442108	3^	INJ&P	Hand fracture/ Fracture of proximal phalanx of second finger of left hand	2	03NOV2020	20/9	2	No	O	NA/TC/TCN	R (11NOV2020)	N/N
>55/ C459100 1 4444 44442110	3^	NERV	Headache/ headache	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
>55/ C459100 1 4444 44442128	3^	MUSC	Intervertebral disc protrusion/ Herniated disc.	1	08OCT2020	12/8	1	No	O	NA/TCN	R (15OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
		GENRL	Pyrexia/ Fever	2	17OCT2020	2/1	3	Yes		NA/TC	R (17OCT2020)	N/N
>55/ C459100 1 4444 44442134	3^	GASTR	Diarrhoea/ Diarrhea*		27SEP2020	1/2	1	No	O	NA	R (28SEP2020)	N/N
		METAB	Hyperglycaemia/ Hyperglycemia	2	16OCT2020	2/1	1	No	O	NA/TCN	R (16OCT2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	17OCT2020	3/2	1	Yes		NA/TC	R (18OCT2020)	N/N
>55/ C459100	3^	NERV	Headache/ headache	1	29SEP2020	3/2	1	Yes		NA/TC	R (30SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 4444 44442139 >55/ C459100 1 4444 44442153	3^	NERV	Headache/ headache	1	28SEP2020	2/2	1	Yes		NA/TC	R (29SEP2020)	N/N
		GENRL	Pyrexia/ fever	2	17OCT2020	2/1	2	Yes		NA/TC	R (17OCT2020)	N/N
>55/ C459100 1 4444 44442175	3^	INV	Body temperature increased/ Body temperature increased: thermal record 37.7 C	1	28SEP2020	2/1	1	Yes		NA/TC	R (28SEP2020)	N/N
>55/ C459100 1 4444 44442183	3^	GENRL	Pyrexia/ fever	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 4444 44442191	3^	SKIN	Pruritus/ Itching in both legs	1	28SEP2020	2/6	1	No	O	NA/TC	R (03OCT2020)	N/N
>55/ C459100 1 4444 44442192	3^	NERV	Headache/ Headache	2	23OCT2020	8/15	1	No	O	NA/TC	R (06NOV2020)	N/N
>55/ C459100 1 4444 44442240	3^	GENRL	Asthenia/ asthenia	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 4444 44442246	3^	SKIN	Rash/ Exanthema located on thighs, groin and arms	2	17OCT2020	2/1	1	No	O	NA	R (17OCT2020)	N/N
>55/ C459100 1 4444 44442271	3^	GASTR	Diarrhoea/ Diarrhea	1	29SEP2020	3/2	2	Yes		NA	R (30SEP2020)	N/N
		MUSC	Myalgia/ generalized myalgia	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
>55/ C459100 1 4444 44442289	3^	NERV	Headache/ headache	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 4444 44442290	3^	EYE	Cataract/ Cataracts	2	29OCT2020	15/C	1	No	O	NA	N	N/N
>55/ C459100 1 4444 44442295	3^	MUSC	Pain in extremity/ Pain in left arm.	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 4444 44442316	3^	GENRL	Injection site pain/ Pain at injection site	1	27SEP2020	1/3	1	Yes		NA	R (29SEP2020)	N/N
		GENRL	Fatigue/ Fatigue	1	28SEP2020	2/1	1	No	O	NA	R (28SEP2020)	N/N
>55/ C459100	3^	GENRL	Pyrexia/ fever	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 4444 44442320		NERV	Headache/ headache	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1005 10051223	3	GENRL	Injection site pain/ injection site pain	1	13OCT2020	2/4	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1005 10051232	3	INFEC	Ear infection/ LEFT EAR INFECTION	1	23OCT2020	12/6	2	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C459100 1 1005 10051236	3	GENRL	Chills/ CHILLS	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C459100 1 1005 10051241	3	GENRL	Fatigue/ FATIGUE	1	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
			Injection site pain/ PAIN AT INJECTION SITE	1	14OCT2020	2/5	1	Yes		NA	R (18OCT2020)	N/N
		MUSC	Myalgia/ MYALGIA	1	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	03NOV2020	1/C	2	Yes		NA	N	N/N
			Injection site pain/ INJECTION SITE PAIN	2	03NOV2020	1/C	2	Yes		NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ MYALGIA	2	03NOV2020	1/C	2	Yes		NA	N	N/N
		NERV	Headache/ HEADACHE	2	03NOV2020	1/C	2	Yes		NA	N	N/N
16-55/ C459100 1 1005 10051244	3	NERV	Migraine/ WORSENING OF MIGRAINES	2	07NOV2020	6/1	2	No	O	NA/TC	R (07NOV2020)	N/N
16-55/ C459100 1 1005 10051246	3	GENRL	Injection site pain/ INJECTION SITE PAIN	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
16-55/ C459100 1 1005 10051259	3	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
			Malaise/ MALAISE	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		MUSC	Arthralgia/ SHOULDER ACHING NOT INJECTION ARM	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
			Myalgia/ MYALGIA	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1005 10051270	3	GENRL	Fatigue/ FATIGUE	1	15OCT2020	1/1	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100	3	GENRL	Injection site pain/ INJECTION SITE ARM PAIN	1	17OCT2020	2/4	1	Yes		NA	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1005 10051283	3	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	16OCT2020	1/5	2	Yes		NA	R (20OCT2020)	N/Y
1 1005 10051285		GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	05NOV2020	1/C	1	Yes		NA	N	N/Y
16-55/ C459100 1 1005 10051288	3	INFEC	Tooth abscess/ RIGHT TOOTH ABSCESS	1	20OCT2020	5/17	2	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C459100 1 1005 10051290	3	GENRL	Injection site pain/ INJECTION SITE PAIN	2	05NOV2020	2/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1005 10051302	3	GENRL	Injection site pain/ MILD ARM PAIN AT INJECTION SITE	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1005 10051318	3	GENRL	Pain/ BODY ACHES	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1005 10051332	3	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1005 10051335	3	GENRL	Injection site pain/ TENDERNESS AT INJECTION SITE	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1005 10051340	3	GASTR	Nausea/ NAUSEA	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		GENRL	Injection site pain/ TENDERNESS AT INJECTION SITE	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1005 10051346	3	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1005 10051349	3	GENRL	Fatigue/ FATIGUE	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
			Injection site pain/ PAIN AT INJECTION SITE	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/Y
16-55/ C459100 1 1005 10051361	3	GENRL	Chills/ CHILLS	2	12NOV2020	2/C	2	Yes		NA	N	N/N
			Fatigue/ FATIGUE	2	12NOV2020	2/C	2	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ HEADACHE	2	12NOV2020	2/C	2	Yes		NA	N	N/N
16-55/ C459100 1 1005 10051365	3	GENRL	Injection site pain/ BURNING SENSATION AT INJECTION SITE	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1005 10051368	3	MUSC	Back pain/ WORSENING OF LOWER BACK PAIN	1	04NOV2020	13/C	2	No	O	NA/TC	N	N/N
		NERV	Dizziness/ LIGHTHEADED	1	09NOV2020	18/2	2	No	O	NA	R (10NOV2020)	N/N
16-55/ C459100 1 1005 10051385	3	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C459100 1 1005 10051393	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	30OCT2020	1/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1007 10071307	3	GENRL	Injection site pain/ pain at injection site	1	13OCT2020	2/1	1	Yes		NA	RS (13OCT2020)	N/N
16-55/ C459100 1 1007 10071334	3	GENRL	Chills/ chills	2	04NOV2020	1/C	1	Yes		NA/TC	RG	N/N
			Pyrexia/ fever	2	04NOV2020	1/C	2	Yes		NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1007 10071339	3	MUSC	Pain in extremity/ pain right arm	2	04NOV2020	1/C	2	Yes		NA	RG	N/N
		RESP	Dry throat/ dry throat	2	04NOV2020	1/1	1	Yes		NA	R (04NOV2020)	N/N
		EAR	Vertigo/ Vertigo	2	05NOV2020	3/9	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C459100 1 1007 10071350	3	MUSC	Pain in extremity/ Sore Arm	1	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 1007 10071352	3	GENRL	Pyrexia/ fever	2	06NOV2020	2/3	1	Yes		NA/TC	R (08NOV2020)	N/N
		MUSC	Myalgia/ Myalgia	2	06NOV2020	2/2	2	Yes		NA/TC	R (07NOV2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
		MUSC	Myalgia/ Myalgia	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C459100 1 1007 10071358	3	MUSC	Myalgia/ bilateral quadriceps myalgia	2	13NOV2020	4/C	1	Yes		NA	RG	N/N
16-55/ C459100	3	GENRL	Injection site pain/ Tenderness at injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1007 10071362	3	GASTR	Gingival discomfort/ Gum irritation	1	03NOV2020	16/C	2	No	O	NA	RG	N/N
16-55/ C459100	3	GENRL	Injection site pain/ Tenderness at injection site	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
1 1007 10071367	3	GENRL	Injection site pain/ Injection Site pain	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/Y
16-55/ C459100	3	CARD	Palpitations/ heart palpitations	1	09NOV2020	21/3	1	Yes		NA/TC	R (11NOV2020)	N/N
1 1007 10071368		GASTR	Nausea/ nausea	2	12NOV2020	3/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C459100		NERV	Headache/ headache	2	12NOV2020	3/2	2	Yes		NA/TC	R (13NOV2020)	N/N
1 1007 10071373	3	GENRL	Pyrexia/ Fever	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
16-55/ C459100		NERV	Headache/ Headache	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
1 1007 10071374												
1 1007 10071374												
16-55/ C459100	3	GENRL	Pyrexia/ Fever	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
1 1007 10071382		NERV	Headache/ Headache	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1007 10071385	3	GENRL	Pyrexia/ fever	1	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N
		GENRL	Pyrexia/ fever	2	11NOV2020	2/1	1	Yes		NA/TCN	R (11NOV2020)	N/N
16-55/ C459100 1 1007 10071388	3	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/5	2	Yes		NA	R (25OCT2020)	N/N
		NERV	Headache/ Headache	1	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C459100 1 1007 10071390	3	MUSC	Pain in extremity/ sore arm	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N
		GASTR	Nausea/ Nausea	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		GENRL	Chills/ Chills	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
			Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		NERV	Headache/ Headache	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C459100 1 1007 10071392	3	GENRL	Injection site pain/ Pain at injection site	1	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1007 10071397	3	GENRL	Injection site pain/ pain in injection arm	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1007 10071400	3	GENRL	Pyrexia/ fever	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C459100 1 1007 10071401	3	GENRL	Injection site pain/ injection site pain	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
			Malaise/ Malaise	1	22OCT2020	2/3	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1007 10071404	3	GASTR	Nausea/ nausea	1	23OCT2020	3/1	1	Yes		NA	R (23OCT2020)	N/N
			Vomiting/ vomiting	1	23OCT2020	3/1	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1007 10071406	3	GENRL	Injection site pain/ Pain at injection site	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/Y
16-55/ C459100 1 1007 10071410	3	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/Y
16-55/ C459100	3	GENRL	Pyrexia/ Fever	2	13NOV2020	2/1	1	Yes		NA/TC	R (13NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1007 10071416	3	GENRL	Injection site pain/ injection site pain	2	13NOV2020	2/C	2	Yes		NA/TC	RG	N/N
1 1007 10071421			Injection site pain/ injection site tenderness	2	13NOV2020	2/C	2	Yes		NA/TC	RG	N/N
16-55/ C459100	3	GENRL	Vessel puncture site pain/ Pain at blood draw site*		22OCT2020	1/1	1	No	O	NA	R (22OCT2020)	N/N
1 1007 10071422												
16-55/ C459100	3	GENRL	Vessel puncture site pain/ pain at blood draw site*		22OCT2020	1/2	1	No	O	NA	R (23OCT2020)	N/N
1 1007 10071423												
		GENRL	Chills/ chills	1	27OCT2020	6/2	1	Yes		NA	R (28OCT2020)	N/N
			Fatigue/ fatigue	1	27OCT2020	6/2	1	Yes		NA	R (28OCT2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	13NOV2020	2/2	2	Yes		NA/TC	R (14NOV2020)	N/N
			Pyrexia/ Fever	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
		NERV	Headache/ Headache	2	13NOV2020	2/2	2	Yes		NA/TC	R (14NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Dyspnoea/ shortness of breath	2	13NOV2020	2/1	1	No	O	NA	R (13NOV2020)	N/N
16-55/ C459100 1 1007 10071424	3	GENRL	Injection site pain/ sorness at injection site	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1007 10071426	3	GENRL	Injection site pain/ Injection Site Pain*		22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
		MUSC	Myalgia/ Myalgia (Generalized)	1	24OCT2020	3/2	2	Yes		NA	R (25OCT2020)	N/N
		GENRL	Injection site pain/ injection site tenderness	2	13NOV2020	2/C	1	Yes		NA	RG	N/N
		MUSC	Arthralgia/ arthralgia	2	13NOV2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1007 10071433	3	NERV	Headache/ headache	1	30OCT2020	4/C	2	Yes		NA/TC	RG	N/N
		GASTR	Nausea/ Nausea	1	31OCT2020	5/3	2	Yes		NA	R (02NOV2020)	N/N
		GENRL	Pyrexia/ fever	1	31OCT2020	5/2	1	Yes		NA/TC	R (01NOV2020)	N/N
		GASTR	Vomiting/ Vomiting	1	01NOV2020	6/1	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C459100	3	GENRL	Fatigue/ Fatigue	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1008 10081595		GENRL	Injection site pain/ Injection site pain	1	14OCT2020	2/4	1	Yes		NA	R (17OCT2020)	N/N
			Chills/ Chills	2	03NOV2020	2/2	2	Yes		NA	R (04NOV2020)	N/N
			Fatigue/ Fatigue	2	03NOV2020	2/2	2	Yes		NA	R (04NOV2020)	N/N
			Injection site pain/ Injection site pain	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
			Pain/ Body aches	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
			NERV Headache/ Headache	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
16-55/ C459100 1 1008 10081605	3	GENRL	Chills/ Chills	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
			Fatigue/ Fatigue	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
			Pain/ Body aches	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1008 10081647	3	GENRL	Chills/ Chills	2	10NOV2020	1/C	2	Yes		NA	RG	N/N
			Pain/ Body aches	2	10NOV2020	1/C	2	Yes		NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1008 10081653	3	GENRL	Pyrexia/ Fever	2	10NOV2020	1/C	2	Yes		NA/TC	RG	N/N	
			NERV	Headache/ Headache	2	10NOV2020	1/C	2	Yes		NA/TC	RG	N/N
			Chills/ Chills	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N	
			Pain/ Body aches	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N	
			Pyrexia/ Fever	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N	
16-55/ C459100 1 1008 10081663	3	INFEC	Urinary tract infection/ Urinary tract infection	1	05NOV2020	16/6	1	No	O	NA/TC	R (10NOV2020)	N/N	
16-55/ C459100 1 1008 10081673	3	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N	
16-55/ C459100 1 1008 10081680	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N	
			Chills/ Chills	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N	
			Fatigue/ Fatigue	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1008 10081695	3	UNC	Injection site pain/ Injection site pain	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
			INJECTION SITE PAIN@@/ Injection site pain	1	27OCT2020	2/4	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C459100 1 1008 10081696	3	UNC	KIDNEY STONE@@/ Kidney stone	1	02NOV2020	8/C	1	No	O	NA	RG	N/N
		UNC	INJECTION SITE PAIN@@/ Injection site pain	1	26OCT2020	1/8	1	Yes		NA	R (02NOV2020)	N/N
16-55/ C459100 1 1009 10091206	3	UNC	HEADACHE@@/ Headache	1	31OCT2020	6/1	1	Yes		NA	R (31OCT2020)	N/N
		GASTR	Abdominal pain upper/ LEFT UPPER QUADRANT PAIN	2	08NOV2020	3/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1009 10091244	3	MUSC	Myalgia/ generalized muscle soreness	1	23OCT2020	2/3	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 1 1011 10111214	3	VASC	Hot flush/ Hot Flashes	1	19OCT2020	1/1	1	Yes		NA	R (19OCT2020)	N/N
16-55/ C459100 1 1011 10111227	3	GENRL	Chills/ Chills	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131678	3	INV	Body temperature increased/ Increased Body temperature (99.7)	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
		MUSC	Myalgia/ Generalized Muscle Aches	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	12OCT2020	1/2	2	Yes		NA	R (13OCT2020)	N/Y
			Injection site pain/ INJECTION SITE PAIN	1	12OCT2020	1/3	2	Yes		NA	R (14OCT2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	02NOV2020	1/4	1	Yes		NA	R (05NOV2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
			Pain/ BODY ACHES	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C459100 1 1013 10131681	3	GENRL	Pyrexia/ LOW GRADE FEVER	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
			Fatigue/ FATIGUE	1	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
		NERV	Headache/ HEADACHE	1	13OCT2020	2/5	2	Yes		NA/TC	R (17OCT2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA	1	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
		GENRL	Pain/ BODY ACHES	1	14OCT2020	3/4	2	Yes		NA/TC	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131685	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	13OCT2020	2/6	2	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1013 10131689	3	GENRL	Fatigue/ FATIGUE	2	02NOV2020	1/3	1	Yes		NA/TC	R (04NOV2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C459100 1 1013 10131708	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
		NERV	Headache/ HEADACHE	1	14OCT2020	2/4	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 1013 10131709	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14OCT2020	1/5	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1013 10131713	3	GENRL	Pain/ BODY ACHES	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		NERV	Dizziness/ LIGHTHEADEDNESS	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131718	3	RESP	Oropharyngeal pain/ SORE THROAT	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		GENRL	Chills/ CHILLS	2	04NOV2020	3/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1013 10131729	3	GENRL	Fatigue/ FATIGUE	2	04NOV2020	3/C	1	Yes		NA	RG	N/N
		GENRL	Chills/ CHILLS	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C459100 1 1013 10131737	3	MUSC	Myalgia/ MUSCLE PAIN	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
		GENRL	Injection site pain/ injection site pain	1	15OCT2020	1/4	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1013 10131744	3	GENRL	Chills/ CHILLS	2	10NOV2020	2/C	1	Yes		NA	RG	N/N
		GENRL	Fatigue/ FATIGUE	2	10NOV2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100	3	GENRL	Pain/ BODY ACHES	2	10NOV2020	2/C	1	Yes		NA	RG	N/N
		GENRL	Fatigue/ FATIGUE	1	19OCT2020	1/C	1	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1013 10131752			Injection site pain/ INJECTION SITE PAIN	1	19OCT2020	1/C	1	Yes		NA	RG	N/N
		GENRL	Pain/ BODY ACHES	1	20OCT2020	2/C	1	Yes		NA	RG	N/N
		RESP	Cough/ COUGH	1	20OCT2020	2/C	1	Yes		NA	RG	N/N
			Nasal congestion/ NASAL CONGESTION	1	20OCT2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1013 10131759	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 1 1013 10131771	3	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C459100 1 1013 10131783	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1013 10131793	3	GENRL	Fatigue/ FATIGUE	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1013 10131794	3	NERV	Headache/ FRONTAL HEADACHE	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
		RESP	Oropharyngeal pain/ SORE THROAT	1	22OCT2020	2/5	1	Yes		NA	R (26OCT2020)	N/N
			Productive cough/ PRODUCTIVE COUGH	1	22OCT2020	2/6	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C459100 1 1013 10131796	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1013 10131800	3	GENRL	Fatigue/ FATIGUE	1	22OCT2020	1/2	2	Yes		NA	R (23OCT2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
			Pain/ BODY ACHES	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1013 10131802	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
			Injection site swelling/ INJECTION SITE SWELLING	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100	3	NERV	Headache/ TEMPORAL HEADACHE	1	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1013 10131808												
16-55/ C459100	3	GENRL	Injection site erythema/ INJECTION SITE ERYTHEMA	1	23OCT2020	2/5	1	Yes		NA	R (27OCT2020)	N/N
1 1013 10131817												
			Injection site pain/ INJECTION SITE PAIN	1	23OCT2020	2/5	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C459100	3	GENRL	Injection site pain/ Soreness at IP injection site*		15OCT2020	1/C	1	Yes		NA	RG	N/N
1 1015 10151246												
16-55/ C459100	3	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
1 1015 10151252												
			Pyrexia/ Fever	1	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C459100	3	GENRL	Chills/ chills	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
1 1016 10161333												
			Pyrexia/ fever	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100	3	GASTR	Diarrhoea/ worsening of diarrhea	1	22OCT2020	1/7	2	Yes		NA	R (28OCT2020)	N/N
1 1016 10161342												

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1018 10181314	3	INJ&P	Bone contusion/ Right Rib Contusion	1	24OCT2020	12/11	1	No	O	NA	R (03NOV2020)	N/N
16-55/ C459100 1 1018 10181323	3	GASTR	Nausea/ Nausea	1	16OCT2020	3/3	1	Yes		NA	R (18OCT2020)	N/N
		NERV	Headache/ Headache	1	16OCT2020	3/3	1	Yes		NA/TC	R (18OCT2020)	N/N
		MUSC	Limb discomfort/ Left arm heaviness	2	04NOV2020	1/C	1	Yes		NA	RG	N/Y
		NERV	Headache/ Headache	2	04NOV2020	1/C	1	Yes		NA	RG	N/Y
16-55/ C459100 1 1018 10181324	3	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
		MUSC	Back pain/ Worsening of back pain	1	28OCT2020	15/7	2	No	O	NA	R (03NOV2020)	N/N
		EAR	Vertigo/ Vertigo	2	04NOV2020	1/C	3	Yes		NA	N	N/N
		GENRL	Chills/ Chills	2	04NOV2020	1/C	2	Yes		NA	RG	N/N
			Pain/ Generalized Body aches	2	04NOV2020	1/2	2	Yes		NA	R (05NOV2020)	N/N
			Pyrexia/ Fever	2	04NOV2020	1/C	3	Yes		NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1018 10181326	3	MUSC	Back pain/ Worsening of chronic back pain	2	04NOV2020	1/C	2	No	O	NA	RG	N/N
		GENRL	Injection site pain/ Pain, Injection Site	1	14OCT2020	1/3	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1018 10181329	3	NERV	Headache/ Headache	1	14OCT2020	1/2	2	Yes		NA/TC/TCN	R (15OCT2020)	N/N
		GASTR	Noninfective gingivitis/ Pain/Inflammation, Gums, lower, frontal	1	15OCT2020	2/C	2	Yes		NA/TC/TCN	RG	N/N
		GENRL	Fatigue/ Fatigue	1	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1019 10191290	3	GENRL	Injection site pain/ Soreness at the injection site	1	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N
		GENRL	Injection site pain/ Injection site muscle ache	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1028 10281253	3	GENRL	Pain/ body aches	1	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N
		GENRL	Pyrexia/ fever	1	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N
		GENRL	Chills/ chills	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)				
16-55/ C459100 1 1028 10281256	3	GENRL	Injection site erythema/ injection site redness right arm	2	03NOV2020	1/C	2	Yes		NA	N	N/N				
			Injection site swelling/ injection site swelling right arm	2	03NOV2020	1/C	2	Yes		NA	N	N/N				
			Pain/ body aches	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N				
			Nausea/ nausea	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N				
			Vomiting/ vomiting	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N				
			Pyrexia/ fever	2	05NOV2020	2/2	2	Yes		NA	R (06NOV2020)	N/N				
			16-55/ C459100 1 1028 10281257	3	GENRL	Chills/ chills	2	06NOV2020	2/1	2	Yes		NA	R (06NOV2020)	N/N	
						Pain/ body aches	2	06NOV2020	2/1	2	Yes		NA/TC	R (06NOV2020)	N/N	
						INV	Body temperature increased/ increased body temperature	2	06NOV2020	2/1	2	Yes		NA	R (06NOV2020)	N/N
						16-55/ C459100 1 1028 10281271	3	MUSC	Myalgia/ muscle pain	1	26OCT2020	6/3	2	Yes		NA
NERV	Headache/ worsening headache	1	26OCT2020	6/3	2			Yes		NA	R (28OCT2020)	N/N				

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1028 10281276	3	GASTR	Nausea/ nausea	2	13NOV2020	2/C	2	Yes		NA	N	N/N
		GENRL	Chills/ chills	2	13NOV2020	2/C	2	Yes		NA	N	N/N
		MUSC	Myalgia/ muscle aches	2	13NOV2020	2/C	2	Yes		NA	N	N/N
16-55/ C459100 1 1028 10281287	3	INV	Body temperature increased/ increased body temperature	1	29OCT2020	2/1	2	Yes		NA	R (29OCT2020)	N/N
16-55/ C459100 1 1036 10361126	3	UNC	INJECTION SITE PAIN@@/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/Y
		UNC	HEADACHE@@/ Headache	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
		UNC	LETHARGY@@/ Lethargy	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1036 10361144	3	GENRL	Injection site pain/ Injection Site Pain*		26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	28OCT2020	3/5	1	Yes		NA	R (01NOV2020)	N/N
		GENRL	Pain/ Body Aches	1	28OCT2020	3/5	1	Yes		NA	R (01NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1037 10371336	3	GENRL	Fatigue/ Fatigue	1	29OCT2020	4/3	1	Yes		NA	R (31OCT2020)	N/N
		NERV	Headache/ Headache	1	29OCT2020	4/3	1	Yes		NA	R (31OCT2020)	N/N
		RESP	Rhinorrhoea/ Rhinorrhea	1	29OCT2020	4/3	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C459100 1 1037 10371342	3	GENRL	Chills/ CHILLS	1	20OCT2020	8/1	1	Yes		NA/TC	R (20OCT2020)	N/N
		MUSC	Myalgia/ MUSCLE ACHES	1	20OCT2020	8/1	1	Yes		NA	R (20OCT2020)	N/N
		GASTR	Diarrhoea/ DIARRHEA	2	07NOV2020	2/3	1	Yes		NA	R (09NOV2020)	N/N
		GENRL	Chills/ CHILLS	2	07NOV2020	2/3	1	Yes		NA	R (09NOV2020)	N/N
		GENRL	Pyrexia/ FEVER	2	07NOV2020	2/3	1	Yes		NA	R (09NOV2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	07NOV2020	2/3	2	Yes		NA/TC	R (09NOV2020)	N/N
16-55/ C459100 1 1039 10391199	3	NERV	Headache/ HEADACHE	2	07NOV2020	2/3	2	Yes		NA/TC	R (09NOV2020)	N/N
		GENRL	Injection site pain/ injection site soreness	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1044 10441190	3	GENRL	Fatigue/ worsening fatigue	2	08NOV2020	3/C	1	Yes		NA	RG	N/N
			Pyrexia/ Fever	2	08NOV2020	3/C	1	Yes		NA	RG	N/N
		NERV	Headache/ headache	2	08NOV2020	3/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1047 10471326	3	GENRL	Injection site pruritus/ Itchiness left arm,injection site*		21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		GENRL	Injection site pain/ Left arm soreness, injection site	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1047 10471331	3	INJ&P	Ligament sprain/ right lower leg sprain	1	02NOV2020	12/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1054 10541191	3	GENRL	Injection site pain/ pain at injection site, L arm	1	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1054 10541197	3	GENRL	Fatigue/ tiredness	1	19OCT2020	1/C	1	Yes		NA	N	N/N
		GENRL	Injection site pain/ soreness L arm injection site	1	20OCT2020	2/23	1	Yes		NA	R (11NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1054 10541200	3	GENRL	Chills/ intermittent chills	1	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
			Pain/ diffuse body aches	1	22OCT2020	1/6	1	Yes		NA/TC	R (27OCT2020)	N/N
		NERV	Headache/ headache	1	22OCT2020	1/6	1	Yes		NA/TC	R (27OCT2020)	N/N
		GENRL	Injection site swelling/ injection site swelling L arm	1	31OCT2020	10/2	1	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C459100 1 1054 10541201	3	GENRL	Fatigue/ tiredness	1	22OCT2020	1/20	1	Yes		NA	R (10NOV2020)	N/N
			Pain/ body aches	1	22OCT2020	1/20	1	Yes		NA	R (10NOV2020)	N/N
		NERV	Headache/ intermittent headache	1	22OCT2020	1/20	1	Yes		NA/TC	R (10NOV2020)	N/N
16-55/ C459100 1 1054 10541203	3	GENRL	Injection site pain/ injection site pain	1	24OCT2020	2/5	1	Yes		NA	R (28OCT2020)	N/N
			Pyrexia/ fever (subjective)	1	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
		GENRL	Injection site erythema/ injection site erythema	1	25OCT2020	3/4	1	Yes		NA	R (28OCT2020)	N/N
			Injection site pruritus/ injection site pruritus	1	25OCT2020	3/4	1	Yes		NA	R (28OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1054 10541206	3	GENRL	Chills/ chills	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
		UNC	L ARM - SITE INJECTION PAIN@@/ L arm - site injection pain	1	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C459100 1 1055 10551244	3	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
		MUSC	Arthralgia/ Generalized joint pains	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
		NERV	Headache/ Headache	1	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C459100 1 1055 10551245	3	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	13NOV2020	1/C	1	Yes		NA/TC	N	N/N
		MUSC	Myalgia/ Generalized myalgias	2	13NOV2020	1/2	1	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C459100 1 1055 10551249	3	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1056 10561484	3	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
		MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	1	13OCT2020	2/11	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1056 10561514	3	GASTR	Diarrhoea/ DIARRHEA	2	13NOV2020	9/C	1	No	O	NA	RG	N/N
		RESP	Rhinorrhoea/ RUNNING NOSE	2	13NOV2020	9/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1056 10561540	3	GENRL	Pyrexia/ FEVER	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C459100 1 1056 10561547	3	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1056 10561555	3	GENRL	Pyrexia/ FEVER	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
		MUSC	Arthralgia/ JOINT PAIN	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C459100	3	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1056 10561594	3	GASTR	Diarrhoea/ DIARRHEA	1	29OCT2020	3/4	1	Yes		NA	R (01NOV2020)	N/N
1 1056 10561600		GENRL	Pyrexia/ FEVER	1	29OCT2020	3/4	1	Yes		NA	R (01NOV2020)	N/N
		NERV	Headache/ HEADACHE	1	29OCT2020	3/4	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C459100 1 1056 10561622	3	GENRL	Chills/ CHILLS	1	31OCT2020	4/2	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C459100 1 1057 10571312	3	NERV	Dizziness/ Dizziness	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1057 10571316	3	INV	Body temperature increased/ ELEVATED TEMPERATURE	2	04NOV2020	2/2	2	Yes		NA	R (05NOV2020)	N/N
16-55/ C459100 1 1057 10571320	3	GENRL	Chills/ CHills	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
			Fatigue/ Fatigue	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1057 10571331	3	GENRL	Injection site pain/ Injection site pain	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N	
			MUSC	Myalgia/ Muscle Aches	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
			GENRL	Chills/ CHILLS	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
				Fatigue/ FATIGUE	2	06NOV2020	1/C	1	Yes		NA	N	N/N
				Pyrexia/ FEVER	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C459100 1 1066 10661323	3	GENRL	Fatigue/ fatigue	1	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N	
			NERV	Headache/ headache	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1066 10661331	3	GENRL	Chills/ chills	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
				Pain/ body aches	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1066 10661337	3	GENRL	Injection site pain/ pain at injection site	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1066 10661345	3	GENRL	Fatigue/ fatigue	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1066 10661388	3	UNC	PAIN AT INJECTION SITE@@/ pain at injection site	1	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C459100 1 1071 10711230	3	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
		GENRL	Fatigue/ FATIGUE	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1077 10771247	3	INFEC	Hepatitis A/ HEPATITIS A	1	30OCT2020	12/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1083 10831272	3	RESP	Nasal discomfort/ Bilateral Nostril Irritation	1	22OCT2020	2/C	1	No	O	NA	N	N/N
		GASTR	Vomiting/ Vomiting	2	12NOV2020	2/C	1	Yes		NA	RG	N/N
		GENRL	Pyrexia/ Fever-102.0	2	12NOV2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1083 10831276	3	GENRL	Injection site pain/ Injection Site Pain	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1083 10831281	3	GENRL	Pyrexia/ Low Grade Temperature 99.0 Fahrenheit	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
			Pyrexia/ Fever-100.3 Fahrenheit	2	12NOV2020	2/C	1	Yes		NA	RG	N/N
			Arthralgia/ Joint Pain-Bilateral Shoulders, Bilateral Hips, Right Ankle and Right Elbow	2	12NOV2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1084 10841480	3	CARD	Acute coronary syndrome/ Acute Coronary Syndrome	1	26OCT2020	13/1	3	No	O	NA/TC/TCN	R (26OCT2020)	N/N
			Acute myocardial infarction/ ST-segment elevated MYOCARDIAL INFARCTION	1	26OCT2020	13/1	2	No	O	NA/TC	R (26OCT2020)	Y/N
		INV	Blood creatinine increased/ Elevated Creatinine	1	26OCT2020	13/2	1	No	O	NA	R (27OCT2020)	N/N
		METAB	Hyperglycaemia/ Hyperglycemia	1	26OCT2020	13/2	1	No	O	NA	R (27OCT2020)	N/N
		VASC	Hypertensive urgency/ Hypertensive Urgency	1	26OCT2020	13/4	2	No	O	NA/TC	R (29OCT2020)	N/N
16-55/ C459100 1 1084 10841484	3	RESP	Pleuritic pain/ bilateral Pleuritic lung pain	1	01NOV2020	19/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1087 10871546	3	GENRL	Pyrexia/ Fever	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C459100 1 1087 10871550	3	MUSC	Rotator cuff syndrome/ Worsening of torn rotator cuff - shoulder, right	1	22OCT2020	10/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1087 10871555	3	GASTR	Diarrhoea/ Diarrhea	1	16OCT2020	3/5	2	Yes		NA	R (20OCT2020)	N/N
			Vomiting/ Vomiting	1	16OCT2020	3/5	2	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1087 10871557	3	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	24OCT2020	11/C		Yes		P	UNK	N/N
16-55/ C459100 1 1087 10871584	3	GASTR	Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	1	09NOV2020	15/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1090 10901502	3	GENRL	Chills/ Chills	2	06NOV2020	2/2	2	Yes		NA	R (07NOV2020)	N/N
			Pyrexia/ Fever	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N
		NERV	Headache/ Headache	2	06NOV2020	2/3	1	Yes		NA/TC	R (08NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1090 10901503	3	GENRL	Injection site pain/ Injection site pain-Left arm	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1090 10901507	3	SKIN	Urticaria/ Hives, upper chest	1	19OCT2020	4/4	2	Yes		P/TC	R (22OCT2020)	N/N
16-55/ C459100 1 1090 10901508	3	GENRL	Injection site pain/ Injection site pain-left arm	1	16OCT2020	1/5	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1090 10901509	3	GENRL	Pyrexia/ Fever	1	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N
		GENRL	Chest discomfort/ chest tightness	1	24OCT2020	6/5	1	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C459100 1 1090 10901510	3	GENRL	Fatigue/ Fatigue	2	07NOV2020	2/2	2	Yes		NA	R (08NOV2020)	N/N
			Pyrexia/ Fever	2	07NOV2020	2/1	2	Yes		NA/TC	R (07NOV2020)	N/N
		NERV	Headache/ Headache	2	07NOV2020	2/1	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C459100 1 1090 10901518	3	GENRL	Fatigue/ Fatigue	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)		
16-55/ C459100 1 1090 10901526	3	GENRL	Injection site pain/ Injection site pain-left arm	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N		
			MUSC	Arthralgia/ Joint pains- generalized	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N	
			NERV	Headache/ Headache	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N	
			GENRL	Pain/ Body Aches	2	11NOV2020	1/2	1	Yes		NA/TC	R (12NOV2020)	N/N	
	3	GENRL	Injection site pain/ Injection site pain-left arm	1	21OCT2020	1/6	1	Yes		NA	R (26OCT2020)	N/N		
	16-55/ C459100 1 1090 10901530	3	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/5	2	Yes		NA	R (27OCT2020)	N/N	
				MUSC	Injection site pain/ Injection site pain-right arm	1	23OCT2020	2/5	2	Yes		NA	R (27OCT2020)	N/N
				MUSC	Myalgia/ Muscle aches	1	23OCT2020	2/5	1	Yes		NA	R (27OCT2020)	N/N
				GENRL	Pain/ Body aches	1	24OCT2020	2/2	2	Yes		NA/TC	R (25OCT2020)	N/N
	16-55/ C459100	3	GENRL	Pyrexia/ Fever	1	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N	
GENRL				Fatigue/ Fatigue	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1090 10901538			Injection site pain/ Injection site pain-left arm	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 1 1090 10901544	3	GASTR	Diarrhoea/ Worsening diarrhea	1	24OCT2020	2/3	3	Yes		NA	R (26OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	24OCT2020	2/3	2	Yes		NA	R (26OCT2020)	N/N
			Pyrexia/ Fever	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 1 1091 10911363	3	GASTR	Diarrhoea/ diarrhea	2	05NOV2020	2/C	1	Yes		NA	N	N/N
		GENRL	Chills/ chills	2	05NOV2020	2/C	1	Yes		NA	N	N/N
			Pyrexia/ fever	2	05NOV2020	2/C	1	Yes		NA/TC	N	N/N
		MUSC	Myalgia/ myalgias	2	05NOV2020	2/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1091 10911381	3	MUSC	Myalgia/ myalgias	1	28OCT2020	2/C	1	Yes		NA	N	N/N
		GENRL	Pyrexia/ fever	1	29OCT2020	3/C	1	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1093 10931201	3	INFEC	Pharyngitis streptococcal/ BACTERIAL STREP PHARYNGITIS	1	04NOV2020	13/7	1	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C459100 1 1095 10951274	3	NERV	Headache/ headache	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1095 10951277	3	INJ&P	Ligament rupture/ Right ACL tear	1	19OCT2020	8/C	2	No	O	NA/TC	N	N/N
			Meniscus injury/ right meniscus tear	1	19OCT2020	8/C	2	No	O	NA/TC	N	N/N
16-55/ C459100 1 1095 10951278	3	GASTR	Nausea/ Nausea	1	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
		INFEC	Abscess limb/ Right leg anterior abscess	1	19OCT2020	8/11	3	No	O	NA/TC	R (29OCT2020)	N/N
			Infected bite/ Cellulitis due to spider bite right anterior leg	1	19OCT2020	8/11	3	No	O	NA/TC	R (29OCT2020)	N/N
16-55/ C459100 1 1095 10951280	3	NERV	Headache/ Headache	2	04NOV2020	1/C	1	Yes		NA	N	N/Y
16-55/ C459100	3	GENRL	Injection site pain/ Injection site pain left arm	1	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1095 10951281		METAB	Hyperlipidaemia/ Hyperlipidemia	1	19OCT2020	8/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1095 10951282	3	GENRL	Injection site pain/ injection site pain right arm	1	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
		INJ&P	Ligament sprain/ left fifth toe sprain	1	21OCT2020	10/11	1	No	O	NA	R (31OCT2020)	N/N
16-55/ C459100 1 1095 10951284	3	MUSC	Myalgia/ left deltoid myalgia	1	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1095 10951285	3	NERV	Headache/ headache	1	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/Y
		GENRL	Injection site pain/ injection site pain left arm	1	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
		GENRL	Chills/ chills	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
			Pyrexia/ Fever	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C459100 1 1095 10951286	3	GENRL	Injection site pain/ injection site pain left arm	1	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1095 10951288	3	NERV	Headache/ Headache	1	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/Y
		GENRL	Chills/ chills	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
		MUSC	Pyrexia/ Fever	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
		MUSC	Myalgia/ Myalgias	1	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1095 10951290	3	GENRL	Arthralgia/ Arthralgia	1	15OCT2020	2/4	1	Yes		NA	R (18OCT2020)	N/N
		GENRL	Asthenia/ Weakness	2	05NOV2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1095 10951293	3	GENRL	Chills/ Chills	2	05NOV2020	2/C	1	Yes		NA	RG	N/N
		INV	Heart rate increased/ Elevated Heart Rate	2	05NOV2020	2/C	1	Yes		NA	RG	N/N
		NERV	Headache/ Headache	2	05NOV2020	2/C	1	Yes		NA	RG	N/N
		RESP	Cough/ Cough	2	05NOV2020	2/C	1	Yes		NA	RG	N/N
		GENRL	Chills/ Chills Post Vaccine	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Fatigue/ Fatigue Post Vaccine	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C459100 1 1095 10951294	3	GASTR	Diarrhoea/ diarrhea	1	16OCT2020	1/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1095 10951295	3	GENRL	Injection site pain/ Pain at injection site left arm*		16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
		MUSC	Synovial cyst/ Ganglion cyst right wrist	1	02NOV2020	18/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1095 10951304	3	GENRL	Injection site pain/ injection site pain left arm	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1101 11011107	3	GENRL	Injection site pain/ injection site pain	1	13OCT2020	1/4	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 1 1101 11011115	3	NERV	Headache/ headache	1	21OCT2020	2/C	1	Yes		NA/TC	N	N/N
		RESP	Sinus congestion/ sinus congestion	1	21OCT2020	2/C	1	Yes		NA	N	N/N
		INFEC	Genital herpes/ genital herpes	1	09NOV2020	21/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11110 11101354	3	RESP	Rhinorrhoea/ Rhinorrea	1	16OCT2020	2/8	1	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C459100 11110 11101356	3	GENRL	Pyrexia/ fever	2	07NOV2020	2/1	1	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C459100 11110 11101361	3	GENRL	Injection site pain/ pain at injection site	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
		GENRL	Chills/ chills	2	11NOV2020	2/1	2	Yes		NA/TC	R (11NOV2020)	N/N
		NERV	Headache/ headache	2	11NOV2020	2/1	2	Yes		NA/TC	R (11NOV2020)	N/N
16-55/ C459100 11112 11121266	3	MUSC	Myalgia/ Muscle Ache	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 11112 11121290	3	MUSC	Myalgia/ Muscle Aches	1	13OCT2020	2/2	2	Yes		NA/TC	RS (14OCT2020)	N/N
16-55/ C459100 11112 11121296	3	GASTR	Nausea/ Nausea	1	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100	3	MUSC	Myalgia/ Muscle Aches	1	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1112 11121297		GENRL	Fatigue/ Fatigue	1	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
		NERV	Headache/ Headache	1	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
		GASTR	Nausea/ Nausea	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N
		GENRL	Fatigue/ Fatigue	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
			Pyrexia/ Fever	2	03NOV2020	2/1	2	Yes		NA/TC	R (03NOV2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
		NERV	Headache/ Headache	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
16-55/ C459100 1 1112 11121298	3	GENRL	Injection site pain/ Injection Site Pain, left arm	1	12OCT2020	1/1	1	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C459100 1 1112 11121299	3	GENRL	Pyrexia/ Fever	1	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1112 11121305	3	GENRL	Injection site pain/ Pain at the injection site	1	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11112 11121315	3	GENRL	Vaccination site pain/ Injection site pain, (post vaccination)	1	20OCT2020	2/2	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 11112 11121328	3	GENRL	Fatigue/ Fatigue	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
		MUSC	Myalgia/ Muscle Aches	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 11118 11181110	3	GENRL	Oedema peripheral/ left foot edema	1	08NOV2020	21/C	1	No	O	NA	N	N/N
16-55/ C459100 11118 11181117	3	PSYCH	Anxiety/ worsening of anxiety	1	24OCT2020	4/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 11118 11181121	3	INJ&P	Road traffic accident/ motor vehicle accident	1	31OCT2020	10/1	1	No	O	NA	R (31OCT2020)	N/N
		MUSC	Musculoskeletal chest pain/ muscular chest pain	1	31OCT2020	10/C	1	No	O	NA	RG	N/N
16-55/ C459100 11120 11201334	3	MUSC	Neck pain/ NECK PAIN	1	04NOV2020	20/C	2	No	CND	NA/TC	RG	N/N
16-55/ C459100	3	MUSC	Neck pain/ Neck Pain	2	12NOV2020	3/C	1	No	CND	NA/TC/TCN	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11120 11201346 16-55/ C459100 11122 11221053	3	SKIN	Eczema/ flare up of eczema	1	20OCT2020	8/C	1	No	O	NA	RG	N/N
		GENRL	Fatigue/ very mild fatigue	2	08NOV2020	5/C	1	Yes		NA	N	N/N
		SKIN	Pruritus/ mild body itching	2	08NOV2020	5/C	1	Yes		NA	N	N/N
16-55/ C459100 11123 11231360	3	SKIN	Pruritus/ Pruritus generalized	1	14OCT2020	3/7	1	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C459100 11123 11231365	3	GENRL	Injection site pain/ Pain at injection site	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
			Injection site pruritus/ Injection site pruritus	2	02NOV2020	1/C	1	Yes		NA	RG	N/Y
16-55/ C459100 11123 11231366	3	GASTR	Nausea/ Nausea	1	13OCT2020	2/4	1	Yes		NA/TC	R (16OCT2020)	N/N
		GASTR	Vomiting/ Vomiting	1	15OCT2020	4/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100	3	GENRL	Fatigue/ fatigue	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1129 11291228			Injection site pain/ injection site pain	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
			Pyrexia/ Fever	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
		MUSC	Myalgia/ Increased Muscle Pain	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
16-55/ C459100 1 1129 11291238	3	GENRL	Chills/ chills	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C459100 1 1129 11291244	3	GENRL	Injection site pain/ injection site tenderness-left deltoid	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1131 11311243	3	INJ&P	Fall/ Fall	1	24OCT2020	12/1	2	No	O	NA	R (24OCT2020)	N/N
		MUSC	Musculoskeletal chest pain/ left rib pain	1	24OCT2020	12/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 1 1131 11311253	3	NERV	Somnolence/ somnolence	1	23OCT2020	1/2	2	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100	3	GENRL	Chills/ chills	2	12NOV2020	2/C	1	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1131 11311254			Pain/ body aches	2	12NOV2020	2/C	2	Yes		NA	N	N/N
			Pyrexia/ fever	2	12NOV2020	2/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1133 11331524	3	GENRL	Injection site pain/ soreness at injection site	1	25OCT2020	3/4	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C459100 1 1133 11331526	3	EAR	Ear pain/ left ear pain	1	11NOV2020	20/C	1	No	O	NA/TCN	N	N/N
16-55/ C459100 1 1133 11331532	3	GENRL	Fatigue/ FATIGUE	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
			Injection site pain/ SORENESS AT INJECTION SITE	1	23OCT2020	1/8	1	Yes		NA	R (30OCT2020)	N/N
		NERV	Headache/ HEADACHE	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1133 11331537	3	BLOOD	Lymphadenopathy/ BILATERAL CERVICAL SWOLLEN LYMPH NODES	2	13NOV2020	3/C	1	No	O	NA	N	N/N
		RESP	Oropharyngeal pain/ SORE THROAT	2	13NOV2020	3/C	1	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11133 11331546	3	MUSC	Pain in extremity/ LEFT ARM PAIN	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C459100 11133 11331559	3	RESP	Cough/ COUGH	1	31OCT2020	6/5	1	Yes		NA	R (04NOV2020)	N/N
			Nasal congestion/ NASAL CONGESTION	1	31OCT2020	6/5	2	Yes		NA	R (04NOV2020)	N/N
16-55/ C459100 11133 11331630	3	GENRL	Chills/ CHILLS	1	12NOV2020	15/C	1	No	O	NA	N	N/N
			Pain/ BODY ACHES	1	12NOV2020	15/C	1	No	O	NA	N	N/N
16-55/ C459100 11134 11341416	3	GENRL	Swelling face/ FACIAL SWELLING	1	18OCT2020	4/2	2	Yes		NA/TC	R (19OCT2020)	N/N
		SKIN	Pruritus/ ITCHING	1	18OCT2020	4/2	2	Yes		NA/TC	R (19OCT2020)	N/N
		VASC	Hot flush/ HOT FLASHES	1	18OCT2020	4/2	2	Yes		NA	R (19OCT2020)	N/N
16-55/ C459100 11134 11341420	3	INJ&P	Ligament sprain/ SPRAINED LEFT ANKLE	1	05NOV2020	22/C	2	No	O	NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1135 11351443	3	MUSC	Myalgia/ muscle pain	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
		GENRL	Chills/ chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C459100 1 1135 11351448	3	METAB	Hypokalaemia/ hypokalemia	1	03NOV2020	14/1	1	No	O	NA/TC	R (03NOV2020)	N/N
		MUSC	Neck pain/ neck pain	1	03NOV2020	14/2	3	No	O	NA/TC/TCN	R (04NOV2020)	N/N
		NERV	Headache/ headache	1	03NOV2020	14/2	3	No	O	NA/TC/TCN	R (04NOV2020)	N/N
16-55/ C459100 1 1135 11351450	3	GASTR	Diarrhoea/ loose stool	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1135 11351452	3	GENRL	Chills/ chills	2	10NOV2020	2/C	1	Yes		NA/TC	RG	N/N
			Pain/ bodyaches	2	10NOV2020	2/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1135 11351453	3	GENRL	Fatigue/ fatigue	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1135 11351457	3	INV	Body temperature increased/ elevated temperature	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
		UNC	UTERINE FIBROIDS@@/ uterine fibroids	1	11NOV2020	22/C	1	No		NA	RG	N/N
		UNC	CHILLS@@/ chills	2	14NOV2020	2/C	1	Yes		NA	N	N/N
		UNC	ELEVATED TEMPERATURE@@/ elevated temperature	2	14NOV2020	2/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1135 11351465	3	GENRL	HEADACHE@@/ headache	2	14NOV2020	2/C	1	Yes		NA	N	N/N
		GENRL	Chills/ chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
		NERV	Pain/ body aches	2	12NOV2020	2/1	1	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C459100 1 1135 11351472	3	NERV	Headache/ headache	2	12NOV2020	2/1	1	Yes		NA/TC	R (12NOV2020)	N/N
		GENRL	Injection site pain/ soreness on injection site (left arm)	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
		GENRL	Chills/ chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
		GENRL	Pain/ body aches	2	12NOV2020	2/C	1	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1135 11351476	3	GENRL	Pyrexia/ fever	2	12NOV2020	2/C	1	Yes		NA	RG	N/N
			Injection site pain/ pain at injection site	2	12NOV2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1135 11351482	3	NERV	Pyrexia/ low grade temperature	2	12NOV2020	2/C	1	Yes		NA	RG	N/N
			Headache/ headache	2	12NOV2020	2/C	1	Yes		NA	RG	N/N
		GENRL	Chills/ chills	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
			Chills/ chills	2	11NOV2020	1/2	1	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C459100 1 1135 11351490	3	GENRL	Injection site pain/ pain at injection site	1	23OCT2020	1/4	1	Yes		NA/TC	R (26OCT2020)	N/N
			Pain/ body aches	1	23OCT2020	1/4	1	Yes		NA/TC	R (26OCT2020)	N/N
16-55/ C459100 1 1135 11351491	3	GENRL	Chills/ chills	1	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
			Pain/ body aches	1	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ fatigue	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 11135 11351498	3	GENRL	Pain/ body aches	1	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
16-55/ C459100 11135 11351501	3	GENRL	Chills/ chills	1	25OCT2020	3/2	1	Yes		NA/TC	R (26OCT2020)	N/N
			Pain/ body aches	1	25OCT2020	3/C	1	Yes		NA/TC	RG	N/N
		INV	Body temperature increased/ elevated temperature	1	25OCT2020	3/2	1	Yes		NA/TC	R (26OCT2020)	N/N
		NERV	Headache/ headache	1	25OCT2020	3/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100 11135 11351508	3	GENRL	Injection site pain/ pain at injection site	1	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
			Pain/ body aches	1	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
16-55/ C459100 11135 11351509	3	GENRL	Injection site pain/ pain at injection site	1	23OCT2020	1/4	1	Yes		NA/TC	R (26OCT2020)	N/N
16-55/ C459100	3	GENRL	Pain/ body aches	1	24OCT2020	1/2	1	Yes		NA	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1135 11351514		RESP	Nasal congestion/ nasal congestion	1	24OCT2020	1/3	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C459100 1 1135 11351517	3	GENRL	Pain/ body aches	1	24OCT2020	1/1	1	Yes		NA	R (24OCT2020)	N/N
		NERV	Dizziness/ dizziness	1	24OCT2020	1/1	1	No	O	NA	R (24OCT2020)	N/N
		NERV	Headache/ headache	1	25OCT2020	2/1	1	Yes		NA/TC	R (25OCT2020)	N/N
16-55/ C459100 1 1135 11351518	3	GENRL	Injection site pain/ pain at injection site	1	24OCT2020	1/2	1	Yes		NA/TC	R (25OCT2020)	N/N
		GENRL	Chills/ chills	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
			Fatigue/ fatigue	2	12NOV2020	1/C	1	Yes		NA	RG	N/N
			Injection site pain/ pain at injection site	2	12NOV2020	1/C	1	Yes		NA	RG	N/N
			Pain/ body aches	2	12NOV2020	1/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1135 11351520	3	MUSC	Myalgia/ muscle pain	1	25OCT2020	2/1	1	Yes		NA/TC	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11135 11351525	3	GENRL	Chills/ Chills	1	25OCT2020	2/1	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 11135 11351528	3	GASTR	Diarrhoea/ loose stool	1	26OCT2020	3/1	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C459100 11135 11351530	3	GENRL	Injection site pain/ pain at injection site	1	25OCT2020	2/2	1	Yes		NA/TC	R (26OCT2020)	N/N
		NERV	Headache/ headache	1	25OCT2020	2/2	1	Yes		NA/TC	R (26OCT2020)	N/N
16-55/ C459100 11135 11351542	3	GASTR	Diarrhoea/ diarrhea	1	26OCT2020	1/1	1	Yes		NA	R (26OCT2020)	N/N
		GENRL	Fatigue/ fatigue	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C459100 11135 11351565	3	GENRL	Injection site pain/ pain at injection site	1	27OCT2020	1/2	1	Yes		NA/TC	R (28OCT2020)	N/N
16-55/ C459100 11135 11351566	3	GASTR	Diarrhoea/ diarrhea	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C459100	3	GENRL	Injection site pain/ pain at injection site	1	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11135 11351569		MUSC	Back pain/ right side back pain	1	28OCT2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 11136 11361076	3	MUSC	Pain in extremity/ ARM PAIN (left)*		22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 11136 11361092	3	UNC	FEVER@@/ fever	1	31OCT2020	4/1	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C459100 11136 11361108	3	GENRL	Injection site pain/ injection site pain	1	30OCT2020	2/3	2	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C459100 11139 11391106	3	MUSC	Back pain/ lower back pain	1	03NOV2020	22/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 11140 11401281	3	GENRL	Injection site pain/ Pain at Injection Site	1	13OCT2020	1/C	1	Yes		NA	N	N/Y
16-55/ C459100 11140 11401290	3	GENRL	Injection site pain/ Tenderness at Injection Site	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1140 11401298	3	MUSC	Pyrexia/ Fever	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
			Arthralgia/ Diffuse Arthralgia's	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C459100 1 1140 11401304	3	GENRL	Injection site pain/ Pain at injection site	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1140 11401306	3	NERV	Amnesia/ short term memory loss	1	07NOV2020	17/4	1	No	O	P/TC/TCN	R (10NOV2020)	Y/N
16-55/ C459100 1 1141 11411257	3	GENRL	Paraparesis/ working diagnosis was spastic paraparesis	1	07NOV2020	17/C	3	No	O	P/TC/TCN	RG	Y/N
			Chills/ Chills	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
			Body temperature increased/ Elevated Body Temperature	1	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C459100 1 1141 11411263	3	MUSC	Arthralgia/ Joint Pain	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		GENRL	Injection site pain/ Left Arm Soreness at Injection Site	1	19OCT2020	1/3	2	Yes		NA	R (21OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11141 11411264	3	MUSC	Pain in extremity/ Upper Arm Soreness L Side, deltoid muscle area	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
		GENRL	Injection site haemorrhage/ Ecchymosis at Injection Site	1	22OCT2020	3/5	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C459100 11141 11411266	3	MUSC	Arthralgia/ Left Shoulder Pain in vaccinated arm	1	21OCT2020	1/4	2	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 11141 11411269	3	GENRL	Injection site erythema/ Slight Erythema at Injection Site	1	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C459100 11142 11421289	3	GENRL	Asthenia/ weakness	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
			Fatigue/ fatigue	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
			Injection site pain/ injection site pain	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
			Pain/ generalized body aches	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 11145 11451108	3	MUSC	Arthralgia/ joint pain	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11145 11451112	3	GENRL	Fatigue/ fatigue	1	23OCT2020	2/3	2	Yes		NA	R (25OCT2020)	N/N
			Injection site pain/ injection site pain	1	23OCT2020	2/3	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 11146 11461271	3	GENRL	Injection site pain/ injection site pain left arm	2	09NOV2020	1/C	1	Yes		NA	N	N/N
		MUSC	Myalgia/ Muscle aches	2	09NOV2020	1/C	1	Yes		NA	RG	N/N
		NERV	Headache/ headache	2	09NOV2020	1/2	1	Yes		NA/TC	R (10NOV2020)	N/N
		GENRL	Fatigue/ fatigue	2	10NOV2020	2/C	1	Yes		NA	N	N/N
16-55/ C459100 11146 11461274	3	MUSC	Pain in extremity/ Pain upper left thigh	1	28OCT2020	10/C	2	No	O	NA	RG	N/N
16-55/ C459100 11146 11461276	3	GASTR	Diarrhoea/ Diarrhea	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
		GENRL	Injection site pain/ Injection site pain, left side	2	09NOV2020	1/3	1	Yes		NA/TC	R (11NOV2020)	N/N
		GENRL	Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1146 11461279	3	GENRL	Chills/ Chills post vaccination #1	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y
			Fatigue/ Fatigue post vaccination #1	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y
			Injection site pain/ Injection site pain post vaccination #1	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y
		NERV	Headache/ Headache post vaccination #1	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y
16-55/ C459100 1 1146 11461281	3	GENRL	Injection site pain/ injection site pain, left deltoid	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/Y
16-55/ C459100 1 1146 11461285	3	RESP	Oropharyngeal pain/ Sore Throat	1	22OCT2020	3/18	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C459100 1 1146 11461287	3	GASTR	Diarrhoea/ Diarrhea day 2 following vaccination #1	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
			Nausea/ Nausea on day 2 following vaccination#1	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1146 11461294	3	GENRL	Fatigue/ Fatigue	1	22OCT2020	2/4	1	Yes		NA	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
16-55/ C459100 1 1146 11461302	3	GENRL	Injection site pain/ Injection site pain, left side	1	22OCT2020	2/4	1	Yes		NA	R (25OCT2020)	N/N	
			Injection site pain/ Injection site pain, left arm	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N	
16-55/ C459100 1 1146 11461308	3	GENRL	Pain/ Bodyaches	1	24OCT2020	3/3	1	Yes		NA	R (26OCT2020)	N/N	
			MUSC	Myalgia/ muscle aches	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
			NERV	Headache/ headache	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C459100 1 1146 11461313	3	GENRL	Injection site pain/ Injection site pain day 1 post vaccine*		22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N	
16-55/ C459100 1 1146 11461316	3	GENRL	Injection site pain/ Left sided injection site pain.	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N	
			GASTR	Diarrhoea/ Diarrhea	1	26OCT2020	5/2	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C459100 1 1146 11461317	3	GASTR	Diarrhoea/ Mild diarrhea evening of vax 1	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache day 2 after vax 1	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1146 11461318	3	GENRL	Fatigue/ fatigue post vaccination 1	1	24OCT2020	3/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 1 1146 11461323	3	GASTR	Diarrhoea/ diarrhea	1	30OCT2020	9/4	2	No	O	NA	R (02NOV2020)	N/N
			Vomiting/ vomiting	1	30OCT2020	9/4	2	No	O	NA	R (02NOV2020)	N/N
16-55/ C459100 1 1146 11461326	3	GENRL	Injection site pain/ Injection site pain right arm	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/Y
		GENRL	Fatigue/ Fatigue	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C459100 1 1146 11461329	3	GENRL	Injection site pain/ injection site pain	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 1 1146 11461342	3	GENRL	Injection site pain/ Injection site pain	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		NERV	Headache/ Headache	1	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11146 11461348	3	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C459100 11146 11461354	3	GENRL	Fatigue/ Fatigue post vaccine 1	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
			Injection site pain/ Injection site pain	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
			Pain/ Body aches post vaccine 1	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C459100 11146 11461356	3	GENRL	Injection site pain/ Injection site pain of left arm	1	27OCT2020	1/4	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C459100 11146 11461360	3	NERV	Headache/ Worsening Headaches	1	27OCT2020	1/2	1	Yes		NA/TC	R (28OCT2020)	N/Y
16-55/ C459100 11146 11461364	3	GENRL	Chills/ Chills	1	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C459100 11146 11461372	3	GENRL	Chills/ Chills	1	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N
			Injection site pain/ Injection site pain	1	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11146 11461387	3	RESP	Oropharyngeal pain/ sore throat	1	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C459100 11146 11461390	3	GENRL	Injection site pain/ injection site pain	1	30OCT2020	2/3	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C459100 11146 11461395	3	GENRL	Chills/ Chills	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/Y
16-55/ C459100 11149 11491328	3	GENRL	Injection site pain/ Left arm injection site pain with touch	1	19OCT2020	1/3	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 11149 11491329	3	GENRL	Injection site pain/ mild pain in left arm (injection site)	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 11150 11501122	3	GENRL	Injection site pain/ Pain at injection site	1	16OCT2020	2/4	2	Yes		NA	R (19OCT2020)	N/N
16-55/ C459100 11150 11501137	3	GENRL	Injection site pain/ Burning Sensation of Injection Site	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/Y
16-55/ C459100	3	GENRL	Injection site pain/ Pain at injection site	1	27OCT2020	1/3	2	Yes		NA	R (29OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11150 11501139												
16-55/ C459100	3	GENRL	Chills/ Chills	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
11152 11521517		GENRL	Chills/ Chills	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
			Fatigue/ Fatigue	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
			Injection site pain/ Injection Site Pain	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
			Pyrexia/ Fever 101.7F	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
		MUSC	Myalgia/ Myalgia	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C459100	3	NERV	Headache/ Headache	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N
11152 11521529		GENRL	Pain/ Body Aches	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C459100	3	INFEC	Skin infection/ skin infection right axilla	1	01NOV2020	17/C	1	No	O	NA/TC	N	N/N
11152 11521534												
16-55/ C459100	3	GASTR	Nausea/ Nausea	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11152 11521549		GENRL	Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
			Pain/ Body Aches	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
		VASC	Flushing/ generalized flushing	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C459100 11152 11521560	3	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
			Injection site pain/ Injection Site Pain	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		MUSC	Myalgia/ Myalgia	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
16-55/ C459100 11156 11561231	3	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	05NOV2020	2/5	2	Yes		NA	R (09NOV2020)	N/N
16-55/ C459100 11156 11561294	3	GENRL	Injection site pain/ PAIN IN SITE OF INJECTION	1	03NOV2020	1/4	2	Yes		NA/TC	R (06NOV2020)	N/N
		MUSC	Myalgia/ MYALGIA	1	03NOV2020	1/4	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C459100	3	GENRL	Chills/ Chills	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1170 11701376			Pyrexia/ Fever	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 1 1170 11701381	3	GENRL	Fatigue/ Fatigue	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
			Injection site pain/ Pain at injection site.	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1170 11701383	3	GENRL	Injection site pain/ Injection Site Pain	1	20OCT2020	1/3	2	Yes		NA/TC	R (22OCT2020)	N/N
			Injection site swelling/ Injection Site Swelling	1	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
		NERV	Dysgeusia/ Metallic Taste in Mouth	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
		GENRL	Pyrexia/ Fever	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
		MUSC	Myalgia/ Myalgias	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1170 11701384	3	GENRL	Chills/ Chills	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
			Pyrexia/ Fever	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701388	3	MUSC	Myalgia/ Myalgias	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
		NERV	Headache/ Headache	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
		GENRL	Injection site pain/ Pain in Injection Site	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
		NERV	Dysgeusia/ Strange taste in mouth	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 11170 11701390	3	GENRL	Fatigue/ Fatigue	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
			Injection site pain/ Pain at Injection Site	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
		NERV	Headache/ Headache	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
		GENRL	Chills/ Chills	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
16-55/ C459100	3		Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
			Pyrexia/ Fever	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
		MUSC	Myalgia/ Myalgias	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
		GENRL	Fatigue/ Fatigue	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1170 11701392			Injection site pain/ Injection Site Pain	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
			Pyrexia/ Fever	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		MUSC	Myalgia/ Myalgias	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		NERV	Headache/ Headache	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C459100 1 1170 11701396	3	GENRL	Fatigue/ Fatigue	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		MUSC	Myalgia/ Muscle Pain	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1170 11701398	3	GENRL	Fatigue/ Fatigue	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
			Injection site pain/ Pain at injection site	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1170 11701400	3	GENRL	Injection site pain/ Pain at injection site	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
		NERV	Headache/ Headache	1	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701403	3	GENRL	Chills/ Chills	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		NERV	Headache/ Headache	1	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 11170 11701404	3	GENRL	Chills/ Chills	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
			Injection site pain/ Injection Site Pain	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
		MUSC	Myalgia/ Myalgias	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 11170 11701412	3	GENRL	Injection site pain/ Pain at Injection Site	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 11170 11701416	3	GENRL	Fatigue/ Fatigue	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
			Injection site erythema/ Redness at injection site	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 11170 11701418	3	GENRL	Fatigue/ Fatigue	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701424	3	GENRL	Injection site erythema/ Injection Site Redness	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
			Injection site swelling/ Injection Site Swelling	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
			Injection site pain/ Pain at injection site.	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 11170 11701426	3	GENRL	Chills/ Chills	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 11170 11701428	3	MUSC	Myalgia/ General Muscle Pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		NERV	Headache/ Headache	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		GASTR	Nausea/ Nausea	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		GENRL	Chills/ Chills	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		GENRL	Pyrexia/ Fever	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		MUSC	Myalgia/ Myalgias	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1170 11701430	3	NERV	Headache/ Headache	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		GENRL	Injection site erythema/ Injection Site Redness	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
			Injection site erythema/ Injection site redness	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
		GENRL	Pyrexia/ Fever	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		NERV	Headache/ Headache	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	3	GENRL	Fatigue/ Fatigue	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	3	MUSC	Myalgia/ Muscle Pain	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	3	GENRL	Injection site erythema/ Injection Site Redness	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
			Injection site pain/ Injection Site Pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11170 11701442	3	GENRL	Chills/ Chills	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
			Injection site pain/ Injection Site Pain	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
		MUSC	Myalgia/ Myalgias	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C459100 11170 11701443	3	GENRL	Injection site pain/ Injection Site Pain	1	23OCT2020	1/4	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C459100 11170 11701444	3	GENRL	Injection site pain/ Pain at injection site	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
		MUSC	Myalgia/ Muscle Pain	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 11170 11701451	3	GENRL	Injection site pain/ Pain at injection site	1	26OCT2020	1/5	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C459100 11170 11701452	3	GENRL	Injection site swelling/ Injection Site Swelling	1	26OCT2020	1/4	1	Yes		NA	R (29OCT2020)	N/N
		GASTR	Nausea/ Nausea	2	13NOV2020	1/C	2	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Vomiting/ Vomiting	2	13NOV2020	1/C	2	Yes		NA	N	N/N
		GENRL	Chills/ Chills	2	13NOV2020	1/C	2	Yes		NA	N	N/N
			Injection site pain/ Injection Site Pain	2	13NOV2020	1/C	2	Yes		NA	RG	N/N
		GENRL	Pyrexia/ Fever	2	14NOV2020	2/C	2	Yes		NA	N	N/N
		SKIN	Night sweats/ Night Sweats	2	14NOV2020	2/C	2	Yes		NA	N	N/N
16-55/ C459100 11170 11701456	3†	GENRL	Injection site erythema/ Redness at injection site	1	02NOV2020	8/1	1	Yes		NA	R (02NOV2020)	N/N
			Injection site swelling/ Swelling at injection site	1	02NOV2020	8/1	1	Yes		NA	R (02NOV2020)	N/N
16-55/ C459100 11170 11701466	3	GENRL	Injection site pain/ Pain at injection site	1	26OCT2020	1/4	1	Yes		NA	R (29OCT2020)	N/N
		GENRL	Chills/ Chills	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
			Fatigue/ Fatigue	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
		MUSC	Myalgia/ Muscle Pain	1	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C459100	3	GENRL	Fatigue/ Fatigue	1	28OCT2020	1/4	1	Yes		NA	R (31OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1170 11701482			Malaise/ Malaise	1	28OCT2020	1/4	1	Yes		NA	R (31OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	29OCT2020	2/3	2	Yes		NA	R (31OCT2020)	N/N
		GENRL	Chills/ Chills	1	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
			Pyrexia/ Fever	1	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
		MUSC	Myalgia/ Myalgias	1	29OCT2020	2/3	2	Yes		NA	R (31OCT2020)	N/N
		NERV	Headache/ Headache	1	29OCT2020	2/3	2	Yes		NA	R (31OCT2020)	N/N
16-55/ C459100 1 1177 11771501	3	GENRL	Chills/ Chills	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C459100 1 1177 11771510	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1177 11771539	3	GENRL	Chest pain/ Chest Pain	1	20OCT2020	1/C	1	No	O	NA	N	N/N
16-55/ C459100	3	INFEC	Gonorrhoea/ gonorrhea	2	04NOV2020	2/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1178 11781296 16-55/ C459100	3	INFE	Hordeolum/ Left eye sty	1	19OCT2020	6/C	2	No	O	NA/TC	N	N/N
1 1178 11781300 16-55/ C459100	3	GENRL	Chills/ chills	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
1 1178 11781309			Injection site pain/ soreness at injection site	1	21OCT2020	2/5	1	Yes		NA	R (25OCT2020)	N/N
		MUSC	Myalgia/ myalgias	1	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N
		GENRL	Chills/ chills	2	12NOV2020	1/C	1	Yes		NA	N	N/N
			Injection site pain/ pain at injection site	2	12NOV2020	1/C	1	Yes		NA	N	N/N
		MUSC	Myalgia/ generalized muscle ache	2	12NOV2020	1/C	1	Yes		NA/TC	N	N/N
		NERV	Headache/ headache	2	12NOV2020	1/C	1	Yes		NA	N	N/N
16-55/ C459100 1 1178 11781310	3	GENRL	Axillary pain/ left axillary pain	2	13NOV2020	2/C	2	Yes		NA	N	N/N
			Fatigue/ fatigue	2	13NOV2020	2/C	2	Yes		NA	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11194 11941030	3	MUSC	Injection site pain/ pain at injection site	2	13NOV2020	2/C	2	Yes		NA	N	N/N
			Myalgia/ body aches/myalgia	2	13NOV2020	2/C	2	Yes		NA	N	N/N
			Headache/ headache	2	13NOV2020	2/C	2	Yes		NA	N	N/N
		NERV	Asthma/ Worsening of Asthma	2	07NOV2020	1/C	2	Yes		NA	N	N/N
16-55/ C459100 11194 11941069	3	RESP	Oropharyngeal pain/ sore throat	1	06NOV2020	18/3	2	No	O	NA	R (08NOV2020)	N/N
16-55/ C459100 11195 11951009	3	NERV	Sciatica/ Lumboischialgia	1	02NOV2020	19/C	1	No	O	NA/TCN	RG	N/N
16-55/ C459100 11195 11951023	3	MUSC	Intervertebral disc protrusion/ herniated disc cervical vertebra	2	11NOV2020	8/C	1	No	O	NA	RG	Y/N
16-55/ C459100 11195 11951030	3	NERV	Sciatica/ Lumboischialgia	1	19OCT2020	4/C	1	No	O	NA	N	N/N
16-55/ C459100 11195 11951100	3	GASTR	Vomiting/ Emesis	1	18OCT2020	1/1	1	No	O	NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11195 11951141	3	MUSC	Intervertebral disc protrusion/ herniated disc thoracic spine	1	21OCT2020	2/C	2	No	O	NA/TC/TCN	RG	N/N
		MUSC	Osteochondrosis/ Osteochondrosis	1	02NOV2020	14/C	1	No	O	NA	N	N/N
			Scoliosis/ Scoliosis	1	02NOV2020	14/C	1	No	O	NA	N	N/N
		MUSC	Intervertebral disc protrusion/ herniated disc cervical spine	1	09NOV2020	21/C	1	No	O	NA	RG	N/N
16-55/ C459100 11195 11951148	3	MUSC	Spinal disorder/ cervical spine syndrome	1	02NOV2020	14/C	1	No	O	NA/TC	RG	N/N
16-55/ C459100 11197 11971003	3	VASC	Hypertension/ hypertension	1	01NOV2020	18/C	2	No	O	NA/TC	RG	N/N
16-55/ C459100 11197 11971019	3	NERV	Dizziness/ lightheadedness	1	22OCT2020	7/1	2	No	O	NA/TC	R (22OCT2020)	N/N
16-55/ C459100 11197 11971028	3	PSYCH	Adjustment disorder with depressed mood/ reactive depression	2	12NOV2020	9/C	1	No	O	NA/TCN	N	N/N
16-55/ C459100 11197 11971039	3	VASC	Hypertension/ worsening hypertension	1	01NOV2020	16/C	2	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11197 11971096	3	NERV	Migraine/ worsening migraine	1	21OCT2020	3/3	2	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C459100 11203 12031004	3	REPRO	Dysmenorrhoea/ menstrual pain	1	04NOV2020	20/1	2	No	O	NA/TC	R (04NOV2020)	N/N
16-55/ C459100 11203 12031015	3	NERV	Headache/ headache	1	28OCT2020	10/5	3	No	O	NA/TC	R (01NOV2020)	N/N
		NERV	Headache/ headache	1	05NOV2020	18/1	2	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C459100 11203 12031026	3	NERV	Headache/ headache	1	07NOV2020	19/1	2	No	O	NA/TC	R (07NOV2020)	N/N
16-55/ C459100 11203 12031031	3	SKIN	Urticaria/ urticaria upper and lower body	1	22OCT2020	3/7	2	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C459100 11203 12031033	3	NERV	Aphasia/ dysphasia	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
		NERV	Dizziness/ dizziness	2	13NOV2020	3/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C459100	3	INFEC	Rhinitis/ rhinitis	1	02NOV2020	13/C	1	No	O	NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1203 12031037		INFEC	Oral herpes/ herpes labialis	1	07NOV2020	18/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1203 12031044	3	NERV	Headache/ headache	1	04NOV2020	15/1	2	No	O	NA/TC	R (04NOV2020)	N/N
		GASTR	Odynophagia/ pain when swallowing	1	05NOV2020	16/4	1	No	O	NA	R (08NOV2020)	N/N
16-55/ C459100 1 1203 12031051	3	INFEC	Pustule/ pustulas	1	26OCT2020	4/6	1	No	O	NA	R (31OCT2020)	N/N
16-55/ C459100 1 1203 12031058	3	INFEC	Rhinitis/ rhinitis	1	06NOV2020	15/C	2	No	O	NA	RG	N/N
16-55/ C459100 1 1203 12031069	3	NERV	Headache/ headache	1	14NOV2020	20/1	2	No	O	NA/TC	R (14NOV2020)	N/N
16-55/ C459100 1 1204 12041214	3	GENRL	Chills/ chills	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
			Malaise/ body malaise	1	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1204 12041220	3	GASTR	Abdominal discomfort/ stomach discomfort	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		MUSC	Pain in extremity/ left arm pain	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C459100 1 1204 12041222	3	NERV	Headache/ Headache	1	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1204 12041227	3	GENRL	Vaccination site pain/ left arm soreness (vac #1 injection site)	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
		GASTR	Nausea/ Nausea	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N
		GENRL	Injection site pain/ pain at injection site	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
			Pyrexia/ Low grade fever, 100.4	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
		MUSC	Myalgia/ Muscle aches	2	03NOV2020	1/3	2	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C459100 1 1204 12041234	3	GENRL	Fatigue/ Fatigue	1	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
			Injection site pain/ Muscle tenderness at injection site	1	15OCT2020	2/4	1	Yes		NA/TC	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		BLOOD	Lymphadenopathy/ Swollen, tender left axillary lymph node	1	17OCT2020	4/6	1	Yes		NA	R (22OCT2020)	N/N
		GENRL	Injection site pain/ Muscle tenderness at injection site	2	04NOV2020	1/3	1	Yes		NA/TC	R (06NOV2020)	N/N
		BLOOD	Lymphadenopathy/ Right axillary lymph node swelling	2	05NOV2020	2/C	1	Yes		NA	RG	N/N
		GENRL	Chills/ Chills	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
			Pyrexia/ Low grade fever, 100.7	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
		NERV	Headache/ Headache	2	05NOV2020	2/2	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C459100 1 1204 12041236	3	GENRL	Vaccination site pain/ left arm soreness (vac#1 injection site)	1	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1204 12041237	3	GENRL	Vaccination site pain/ left arm soreness (vac #1 injection site)	1	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1204 12041239	3	GENRL	Vaccination site pain/ left arm soreness (vac#1 injection site)	1	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100	3	NERV	Headache/ Headache	1	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1204 12041240												
16-55/ C459100 1 1204 12041253	3	GENRL	Fatigue/ fatigue	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
			Vaccination site pain/ left arm soreness (vac#1 injection site)	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1204 12041255	3	GENRL	Vaccination site pain/ left arm soreness (vac#1 injection site)	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
		GENRL	Fatigue/ fatigue	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
			Pyrexia/ low grade fever; temp 100 F	1	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 1204 12041259	3	GENRL	Fatigue/ Fatigue	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
			Injection site pain/ Pain at injection site	1	16OCT2020	1/4	1	Yes		NA	R (19OCT2020)	N/N
			Pyrexia/ fever - 101.0	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1204 12041263	3	MUSC	Pain in extremity/ Left Arm Pain	1	19OCT2020	1/4	1	Yes		NA	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1204 12041268	3	GENRL	Fatigue/ Fatigue	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
		GENRL	Malaise/ Body Malaise	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
		GENRL	Vaccination site pain/ Left Arm Soreness (Vaccination #1 Injection Site)	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1204 12041274	3	GENRL	Injection site pain/ Muscle tenderness at injection site	1	21OCT2020	1/3	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C459100 1 1204 12041275	3	GENRL	Vaccination site pain/ left arm soreness (vac#1 injection site)	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1204 12041283	3	NERV	Headache/ headache	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
		GENRL	Chills/ chills	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		NERV	Pyrexia/ low grade fever, 101.0	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		NERV	Headache/ headache	2	12NOV2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1204 12041283	3	NERV	Headache/ Headache	1	24OCT2020	2/1	2	Yes		NA	R (24OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Injection site pain/ Muscle Tenderness at the injection site	2	11NOV2020	1/C	1	Yes		NA	RG	N/N
		GENRL	Chills/ Chills	2	12NOV2020	2/C	1	Yes		NA	RG	N/N
			Pyrexia/ Low Grade Fever 101.2	2	12NOV2020	2/C	2	Yes		NA/TC	RG	N/N
		MUSC	Myalgia/ Muscle Aches	2	12NOV2020	2/C	1	Yes		NA	RG	N/N
		NERV	Headache/ Headache	2	12NOV2020	2/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1204 12041287	3	MUSC	Myalgia/ myalgia	1	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
		GENRL	Fatigue/ fatigue	1	25OCT2020	3/2	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C459100 1 1204 12041293	3	GENRL	Pyrexia/ fever	2	14NOV2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1204 12041294	3	MUSC	Myalgia/ muscle aches	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
		NERV	Headache/ headache	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1205 12051028	3	INV	Blood pressure increased/ Increasing of systolic and diastolic blood pressure*		30OCT2020	/1	2	No	O	NA/W	R (30OCT2020)	N/N
16-55/ C459100 1 1209 12091002	3	NERV	Headache/ Headache	1	12NOV2020	21/C	1	No	O	NA	RG	N/N
16-55/ C459100 1 1209 12091013	3	GENRL	Chest pain/ Chest Pain	1	08NOV2020	7/2	1	No	O	NA	R (09NOV2020)	N/N
16-55/ C459100 1 1210 12101002	3	INFEC	Nasopharyngitis/ Cold	1	27OCT2020	6/6	2	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C459100 1 1210 12101029	3	MUSC	Arthralgia/ joint pain	1	04NOV2020	6/2	3	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C459100 1 1210 12101049	3	MUSC	Neck pain/ neck pain	1	09NOV2020	6/C	1	No	O	NA	N	N/N
16-55/ C459100 1 1214 12141025	3	INFEC	Pyelonephritis/ Pyelonephritis	1	09NOV2020	7/C	1	No	O	NA/TC	N	N/N
16-55/ C459100	3	GENRL	Injection site pain/ Injection site pain	1	10NOV2020	21/C	1	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1218 12181004			Injection site swelling/ Injection site swelling	1	10NOV2020	21/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1218 12181011	3	GENRL	Injection site pain/ injection site pain	1	02NOV2020	1/5	1	Yes		NA	R (06NOV2020)	N/Y
16-55/ C459100 1 1219 12191022	3	INFEC	Onychomycosis/ onychomycosis	1	29OCT2020	10/C	2	No	O	NA/TC	N	N/N
		METAB	Type 2 diabetes mellitus/ Diabetes Mellitus Type 2	1	29OCT2020	10/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1219 12191028	3	GENRL	Fatigue/ Fatigue	1	30OCT2020	4/7	1	Yes		NA	R (05NOV2020)	N/N
		MUSC	Back pain/ Low Back Pain	1	02NOV2020	7/4	1	Yes		NA	R (05NOV2020)	N/N
			Myalgia/ Muscle aches	1	02NOV2020	7/4	1	Yes		NA	R (05NOV2020)	N/N
16-55/ C459100 1 1219 12191030	3	GENRL	Fatigue/ tiredness	1	29OCT2020	1/C	1	Yes		NA	N	N/Y
		NERV	Headache/ slight headache	1	29OCT2020	1/C	1	Yes		NA	N	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1219 12191034	3	GENRL	Pain/ Body aches	1	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N
		NERV	Headache/ Headache	1	03NOV2020	6/1	1	Yes		NA	R (03NOV2020)	N/N
		GENRL	Injection site pain/ mild soreness at injection site	1	12NOV2020	1/C	1	Yes		NA	N	N/Y
16-55/ C459100 1 1220 12201018	3	NERV	Headache/ headache	1	18OCT2020	3/1	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1220 12201020	3	GASTR	Hypoaesthesia/ facial numbness	1	18OCT2020	3/16	1	No	O	NA	R (02NOV2020)	N/N
			Hypoaesthesia/ leg numbness	1	18OCT2020	3/25	1	No	O	NA	R (11NOV2020)	N/N
			Diarrhoea/ diarrhea	1	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N
16-55/ C459100 1 1220 12201022	3	GENRL	Injection site pain/ soreness at injection site	1	20OCT2020	1/8	1	Yes		NA	R (27OCT2020)	N/Y
16-55/ C459100 1 1220 12201026	3	GENRL	Fatigue/ tiredness	1	27OCT2020	1/1	1	Yes		NA	R (27OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1221 12211003	3	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1221 12211005	3	GASTR	Diarrhoea/ Diarrhea	1	19OCT2020	5/5	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1221 12211007	3	INFEC	Abscess jaw/ Abscess in left jaw	1	31OCT2020	16/C	3	No	O	NA/TC/TCN	N	N/N
		INFEC	Meningitis bacterial/ Meningitis Bacterial	1	10NOV2020	26/C	3	No	O	NA/TC	N	Y/N
16-55/ C459100 1 1221 12211013	3	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1221 12211014	3	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/2	2	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C459100 1 1223 12231242	3	GENRL	Fatigue/ fatigue	1	14OCT2020	1/3	2	Yes		NA	R (16OCT2020)	N/N
		MUSC	Pain in extremity/ left arm soreness	1	14OCT2020	1/4	2	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100	3	GENRL	Pyrexia/ fever	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1223 12231244		MUSC	Pain in extremity/ sore arm post vaccine	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1223 12231246	3	NERV	Headache/ headache	1	30OCT2020	16/3	2	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C459100 1 1226 12262141	3	GENRL	Injection site erythema/ Redness at the injection site	1	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N
			Injection site pain/ Pain at the injection site	1	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N
		GENRL	Chills/ Chills	1	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
		INV	Body temperature increased/ elevated body temperature (37.7 C)	1	14OCT2020	2/2	2	Yes		NA/TC	R (15OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1226 12262146	3	MUSC	Arthralgia/ joint pain	1	16OCT2020	4/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1226 12262151	3	GENRL	Injection site pain/ Pain at the injection site	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12262153	3	MUSC	Myalgia/ Muscle pain	2	03NOV2020	1/C	1	Yes		NA	RG	N/N
		NERV	Headache/ Headache	2	03NOV2020	1/C	1	Yes		NA	RG	N/N
16-55/ C459100 1 1226 12262159	3	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1226 12262163	3	GENRL	Injection site pain/ Pain at the injection site	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
		NERV	Headache/ Headache	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1226 12262170	3	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1226 12262184	3	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	1/4	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C459100 1 1226 12262185	3	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	1/3	2	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100	3	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12262186 16-55/ C459100 1 1226 12262198	3	GENRL	Chills/ chills	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
			Injection site pain/ pain at injection site	1	15OCT2020	1/5	1	Yes		NA	R (19OCT2020)	N/N
		NERV	Somnolence/ somnolence	1	15OCT2020	1/2	2	Yes		NA	R (16OCT2020)	N/N
		GENRL	Chills/ chills	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
			Injection site pain/ pain at injection site	2	04NOV2020	1/C	1	Yes		NA	RG	N/N
			Pyrexia/ fever (38 C)	2	04NOV2020	1/2	1	Yes		NA/TC	R (05NOV2020)	N/N
		NERV	Somnolence/ somnolence	2	04NOV2020	1/C	2	Yes		NA	RG	N/N
16-55/ C459100 1 1226 12262201	3	GENRL	Chills/ chills	2	04NOV2020	1/C	2	Yes		NA/TC	RG	N/N
			Injection site pain/ pain at injection site	2	04NOV2020	1/C	2	Yes		NA/TC	RG	N/N
		MUSC	Myalgia/ muscle pain	2	04NOV2020	1/C	2	Yes		NA/TC	RG	N/N
16-55/ C459100	3	GENRL	Injection site pain/ Pain at injection site	1	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12262211												
16-55/ C459100	3	MUSC	Myalgia/ muscle pain	1	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
1 1226 12262212												
16-55/ C459100	3	GENRL	Injection site pain/ Pain at the injection site	1	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
1 1226 12262219												
		GENRL	Injection site pain/ pain at injection site	2	05NOV2020	1/C	1	Yes		NA/TC	RG	N/N
		GENRL	Asthenia/ weakness	2	06NOV2020	2/C	1	Yes		NA/TC	RG	N/N
		NERV	Headache/ headache	2	06NOV2020	2/C	1	Yes		NA/TC	RG	N/N
16-55/ C459100	3	GENRL	Injection site pain/ Pain at the injection site	1	15OCT2020	1/5	2	Yes		NA	R (19OCT2020)	N/N
1 1226 12262220												
		NERV	Headache/ Headache	1	15OCT2020	1/5	2	Yes		NA	R (19OCT2020)	N/N
16-55/ C459100	3	NERV	Headache/ headache	1	16OCT2020	1/2	1	Yes		NA/TC	R (17OCT2020)	N/N
1 1226 12262223												
16-55/ C459100	3	GENRL	Injection site pain/ Pain at injection site	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12262225		GENRL	Malaise/ Malaise	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1226 12262228	3	NERV	Headache/ Headache	1	16OCT2020	1/2	2	Yes		NA/TC	RS (17OCT2020)	N/N
16-55/ C459100 1 1226 12262236	3	GENRL	Injection site pain/ Pain at the injection site	1	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1226 12262237	3	GENRL	Injection site pain/ Pain at the injection site	1	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
		GENRL	Chills/ Chills	2	05NOV2020	1/2	2	Yes		NA	R (06NOV2020)	N/N
			Fatigue/ Fatigue	2	05NOV2020	1/2	2	Yes		NA	R (06NOV2020)	N/N
			Injection site pain/ Pain at the injection site	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C459100 1 1226 12262239	3	GENRL	Injection site pain/ Pain at the injection site	1	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100	3	GENRL	Injection site pain/ pain at injection site	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12262243	3	GENRL	Fatigue/ Fatigue	1	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
1 1226 12262245	3†	MUSC	Myalgia/ muscle pain	1	19OCT2020	4/4	2	Yes		NA/TC	R (22OCT2020)	N/N
1 1226 12262255		GASTR	Nausea/ Nauseas	2	06NOV2020	1/C	3	Yes		NA	RG	N/N
			Vomiting/ Vomiting	2	06NOV2020	1/C	3	Yes		NA/TC	RG	N/N
		GENRL	Chills/ Chills	2	06NOV2020	1/C	3	Yes		NA	RG	N/N
			Injection site pain/ Pain at the injection site	2	06NOV2020	1/C	3	Yes		NA	RG	N/N
			Pyrexia/ Fever 39 C	2	06NOV2020	1/C	3	Yes		NA/TC	RG	N/N
		MUSC	Myalgia/ Muscle pain	2	06NOV2020	1/C	3	Yes		NA/TC	RG	N/N
16-55/ C459100 1 1226 12262258	3	GENRL	Injection site pain/ Pain at injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100	3	GENRL	Chills/ Chills	1	17OCT2020	1/2	2	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12262263			Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	2	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1226 12262270	3	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/3	2	Yes		NA/TC	R (19OCT2020)	N/N
			Pyrexia/ Fever 38 C	1	17OCT2020	1/3	2	Yes		NA/TC	R (19OCT2020)	N/N
16-55/ C459100 1 1226 12262273	3	GENRL	Injection site pain/ Pain at injection site	1	17OCT2020	1/3	2	Yes		NA/TC	R (19OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	17OCT2020	1/3	2	Yes		NA/TC	R (19OCT2020)	N/N
16-55/ C459100 1 1226 12262276	3	GENRL	Injection site pain/ Pain at injection site	1	17OCT2020	1/2	1	Yes		NA	RS (18OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	2	07NOV2020	2/1	1	Yes		NA/TC	R (07NOV2020)	N/N
		NERV	Headache/ Headache	2	07NOV2020	2/1	1	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C459100 1 1226 12262284	3	GENRL	Asthenia/ Asthenia	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12262286	3	GASTR	Diarrhoea/ Diarrhea	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
			Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 1226 12262291	3	GENRL	Injection site oedema/ edema at injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
			Injection site pain/ pain at injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1226 12262292	3	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
		NERV	Headache/ Headache	1	17OCT2020	1/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100 1 1226 12262293	3	GENRL	Fatigue/ Fatigue	1	19OCT2020	3/3	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 1 1226 12262295	3	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	2	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12262299	3	GASTR	Nausea/ Nauseas	1	18OCT2020	2/3	1	Yes		NA	R (20OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	18OCT2020	2/3	1	Yes		NA/TC	R (20OCT2020)	N/N
		NERV	Headache/ Headache	1	18OCT2020	2/3	1	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C459100 1 1226 12262304	3	GENRL	Injection site pain/ Pain at the injection site	1	18OCT2020	2/2	1	Yes		NA	R (19OCT2020)	N/N
16-55/ C459100 1 1226 12262307	3	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1226 12262315	3	GENRL	Injection site pain/ Pain at injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1226 12262317	3	GENRL	Injection site pain/ Pain at the injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1226 12262319	3	GENRL	Chills/ Chills	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
			Injection site pain/ Pain at injection site	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1226 12262321	3	GENRL	Chills/ Chills	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1226 12262327	3	GENRL	Injection site pain/ Pain at the injection site	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
			Malaise/ Unspecified malaise	1	19OCT2020	1/3	2	Yes		NA	R (21OCT2020)	N/N
			Pyrexia/ Fever 38 C	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 1 1226 12262329	3	MUSC	Arthralgia/ Arthralgia (knees and ankles)	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1226 12262331	3	GENRL	Chills/ Chills	1	19OCT2020	1/2	2	Yes		NA/TC	R (20OCT2020)	N/N
			Injection site pain/ Pain at the injection site	1	19OCT2020	1/2	2	Yes		NA/TC	R (20OCT2020)	N/N
		GENRL	Chills/ Chills	2	08NOV2020	2/1	2	Yes		NA	R (08NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12262334	3	MUSC	Myalgia/ Muscle pain	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
		NERV	Headache/ Headache	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1226 12262335	3	GENRL	Pain/ body aches	1	20OCT2020	2/4	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C459100 1 1226 12262338	3	GENRL	Pain/ body aches	1	21OCT2020	3/1	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 1 1226 12262340	3	GASTR	Diarrhoea/ Diarrhea	1	19OCT2020	1/1	1	Yes		NA	R (19OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1226 12262347	3	GENRL	Fatigue/ Fatigue	1	19OCT2020	1/3	1	Yes		NA/TC	RS (21OCT2020)	N/N
			Injection site pain/ Pain at injection site	1	19OCT2020	1/3	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 1 1226 12262348	3	GENRL	Pyrexia/ Fever 38.3 C	1	23OCT2020	5/3	1	Yes		NA	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1226 12262351	3	GENRL	Injection site pain/ Pain at the injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
		GENRL	Asthenia/ Asthenia	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 1 1226 12262357	3	GENRL	Injection site pain/ Pain at the injection site	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1229 12291215	3†	GASTR	Dyspepsia/ Heartburn	1	02NOV2020	20/C	1	No	O	NA/TC	N	N/N
16-55/ C459100 1 1232 12321354	3	GASTR	Diarrhoea/ Diarrhea	1	06NOV2020	23/1	1	No	O	NA	R (06NOV2020)	N/N
16-55/ C459100 1 1235 12351169	3	GENRL	Pyrexia/ PYREXIA*		21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		MUSC	Myalgia/ MYALGIA	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C459100 1 1235 12351175	3	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	2/1	2	Yes		NA	R (15OCT2020)	N/N
			Pain/ Body aches	1	15OCT2020	2/1	2	Yes		NA	R (15OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1235 12351180	3	MUSC	Myalgia/ Right arm muscle soreness	1	15OCT2020	2/1	2	Yes		NA	R (15OCT2020)	N/N
		GASTR	Nausea/ nausea	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
			Vomiting/ emesis	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
		GENRL	Chills/ rigor	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
		MUSC	Myalgia/ generalized myalgia	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
		NERV	Headache/ cephalgia	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
		GENRL	Pyrexia/ fever 38.5 C	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		MUSC	Pain in extremity/ left arm soreness	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Pyrexia/ pyrexia	2	07NOV2020	2/2	1	Yes		NA/TC	R (08NOV2020)	N/N
16-55/ C459100 1 1235 12351192	3	NERV	Headache/ cephalgia	2	09NOV2020	4/1	1	Yes		NA/TC	R (09NOV2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ Fatigue	1	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N
		MUSC	Myalgia/ Bilateral Shoulder Myalgia	1	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N
			Myalgia/ Right arm myalgia	1	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N
		NERV	Headache/ Headache	2	07NOV2020	2/2	1	Yes		NA/TC	R (08NOV2020)	N/N
		RESP	Oropharyngeal pain/ Sore throat	2	08NOV2020	3/2	1	Yes		NA/TC	R (09NOV2020)	N/N
		RESP	Upper-airway cough syndrome/ Post-nasal drip	2	09NOV2020	4/1	1	Yes		NA	R (09NOV2020)	N/N
16-55/ C459100 1 1235 12351193	3	GENRL	Fatigue/ fatigue	1	19OCT2020	1/2	2	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1235 12351195	3	MUSC	Pain in extremity/ left arm pain	1	19OCT2020	1/3	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 1 1235 12351209	3	GENRL	Fatigue/ fatigue	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		MUSC	Myalgia/ myalgia	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100	3	GASTR	Nausea/ Nausea	2	11NOV2020	2/C	2	Yes		NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1235 12351214		GENRL	Chills/ Chills	2	11NOV2020	2/C	2	Yes		NA/TC	N	N/N
			Pyrexia/ Pyrexia	2	11NOV2020	2/C	1	Yes		NA/TC	N	N/N
16-55/ C459100 1 1235 12351218	3	GENRL	Fatigue/ Fatigue	1	23OCT2020	1/2	2	Yes		NA	R (24OCT2020)	N/N
		MUSC	Myalgia/ Left arm myalgia	1	23OCT2020	1/2	2	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412167	3	GENRL	Fatigue/ Fatigue	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
			Injection site pain/ Injection site pain	1	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C459100 1 1241 12412169	3	GENRL	Injection site pain/ Injection site pain	1	13OCT2020	1/2	1	Yes		NA/TCN	R (14OCT2020)	N/N
16-55/ C459100 1 1241 12412175	3	GENRL	Injection site pain/ Injection site pain	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/Y
16-55/ C459100	3	GENRL	Fatigue/ Prostration	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12412176			Injection site pain/ Injection site pain	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1241 12412177	3	GENRL	Injection site pain/ Injection site pain	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C459100 1 1241 12412179	3	GENRL	Pyrexia/ Fever	1	14OCT2020	1/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C459100 1 1241 12412181	3	GENRL	Injection site pain/ Injection site pain	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1241 12412186	3	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1241 12412187	3	GENRL	Pyrexia/ Fever	1	16OCT2020	3/1	1	Yes		NA/TC	R (16OCT2020)	N/N
		NERV	Headache/ Headache	1	16OCT2020	3/1	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100	3	BLOOD	Lymphadenopathy/ Left armpit lymph node enlargement	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
11241 12412190		GENRL	Medical device pain/ Pain in prosthesis in the left hand	1	15OCT2020	2/16	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C459100 11241 12412194	3	GENRL	Chills/ Chills	1	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
			Fatigue/ Fatigue	1	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
		NERV	Headache/ Headache	1	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C459100 11241 12412201	3	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
			Pyrexia/ Fever	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 11241 12412202	3	GASTR	Nausea/ Nausea	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 11241 12412204	3	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12412207	3	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1241 12412209	3	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	2/3	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1241 12412221	3	MUSC	Myalgia/ Myalgia	1	16OCT2020	2/1	2	Yes		NA	R (16OCT2020)	N/N
16-55/ C459100 1 1241 12412227	3	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/4	2	Yes		NA	R (19OCT2020)	N/N
16-55/ C459100 1 1241 12412232	3	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1241 12412235	3	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1241 12412236	3	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C459100	3	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12412237												
16-55/ C459100 1 1241 12412248	3	GENRL	Fatigue/ Fatigue	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
			Injection site pain/ Injection site pain	1	17OCT2020	2/3	2	Yes		NA/TC	R (19OCT2020)	N/N
16-55/ C459100 1 1241 12412252	3	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N
		NERV	Tremor/ Leg tremors	1	20OCT2020	5/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1241 12412254	3	GENRL	Fatigue/ Fatigue	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
			Fatigue/ Prostration	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1241 12412258	3	GASTR	Nausea/ Nausea	1	17OCT2020	2/4	2	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412267	3	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12412271	3	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1241 12412275	3	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1241 12412278	3	GENRL	Injection site erythema/ Injection site redness	1	16OCT2020	1/4	1	Yes		NA	R (19OCT2020)	N/N
			Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
			Injection site swelling/ Injection site swelling	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
		GENRL	Pyrexia/ Fever	1	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	1	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	1	18OCT2020	3/1	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1241 12412285	3	GENRL	Injection site pain/ Injection site pain	2	05NOV2020	1/C	1	Yes		NA	RG	N/Y
16-55/ C459100	3	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/4	2	Yes		NA	R (19OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12412295		MUSC	Myalgia/ Myalgia	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C459100 1 1241 12412303	3	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412304	3	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	2	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412307	3	GASTR	Nausea/ Nausea	1	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	2	Yes		NA	R (22OCT2020)	N/N
		NERV	Headache/ Headache	1	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412312	3	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA/TCN	R (20OCT2020)	N/N
		EYE	Conjunctivitis allergic/ Allergic conjunctivitis	1	25OCT2020	7/3	1	No	O	NA/TC	R (27OCT2020)	N/N
16-55/ C459100	3	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/C	1	Yes		NA	RG	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12412317												
16-55/ C459100 1 1241 12412320	3	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	2/3	1	Yes		NA/TCN	R (22OCT2020)	N/N
16-55/ C459100 1 1241 12412333	3	MUSC	Arthralgia/ Polyarthralgia	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
			Myalgia/ Myalgia	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412338	3	GENRL	Fatigue/ Prostration	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
			Injection site pain/ Injection site pain	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412339	3	GENRL	Chills/ Chills	1	20OCT2020	2/2	1	Yes		NA/TC	R (21OCT2020)	N/N
			Pyrexia/ Fever	1	20OCT2020	2/2	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C459100 1 1241 12412341	3	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12412342	3	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/Y
16-55/ C459100 1 1241 12412346	3	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	2	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1241 12412348	3	GENRL	Injection site swelling/ Injection site swelling	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412352	3	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
		GENRL	Fatigue/ Prostration	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412353	3	GENRL	Chills/ Chills	1	21OCT2020	3/1	1	Yes		NA	R (21OCT2020)	N/N
			Fatigue/ Fatigue	1	21OCT2020	3/1	1	Yes		NA	R (21OCT2020)	N/N
			Pyrexia/ Fever	1	21OCT2020	3/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 1 1241 12412354	3	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	1	Yes		NA	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12412361	3	GASTR	Nausea/ Nausea	1	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
		GENRL	Fatigue/ Prostration	1	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	2	Yes		NA/TC	R (22OCT2020)	N/N
		GENRL	Chills/ Chills	1	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412363	3	NERV	Pyrexia/ Fever	1	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
			Headache/ Headache	1	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/Y
16-55/ C459100 1 1241 12412365	3	GENRL	Pyrexia/ Fever	1	19OCT2020	1/1	1	Yes		NA/TC	R (19OCT2020)	N/N
16-55/ C459100 1 1241 12412373	3	NERV	Presyncope/ Lipothymia (Presyncope)	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/Y
16-55/ C459100	3	GENRL	Pyrexia/ Fever	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12412375	3	NERV	Headache/ Headache	1	20OCT2020	2/1	2	Yes		NA/TC	R (20OCT2020)	N/N
1 1241 12412377	3	GASTR	Nausea/ Nausea	1	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
1 1241 12412380		GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
		NERV	Headache/ Headache	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1241 12412390	3	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412391	3	GENRL	Chills/ Chills	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
			Fatigue/ Fatigue	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 1 1241 12412398	3	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/5	1	Yes		NA	R (24OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12412399	3	GENRL	Fatigue/ Prostration	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1241 12412401	3	SKIN	Urticaria/ Chest region Urticaria	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 1 1241 12412402	3	GENRL	Pyrexia/ Fever	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 1 1241 12412405	3	NERV	Headache/ Headache	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C459100 1 1241 12412407	3	GENRL	Fatigue/ Fatigue	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 1 1241 12412409	3	GENRL	Pyrexia/ Fever	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
		METAB	Decreased appetite/ Hyporexia	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11241 12412410	3	GASTR	Nausea/ Nausea	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
		NERV	Headache/ Headache	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 11241 12412414	3	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/Y
16-55/ C459100 11241 12412415	3	GENRL	Chills/ Chills	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C459100 11241 12412424	3	GENRL	Fatigue/ Prostration	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 11241 12412425	3	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 11241 12412426	3	NERV	Headache/ Headache	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C459100 11241 12412429	3	GENRL	Pyrexia/ Fever	1	22OCT2020	2/1	1	Yes		NA/TC	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12412438	3	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1241 12412439	3	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
		NERV	Headache/ Headache	1	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 1 1241 12412442	3	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1241 12412445	3	EYE	Eye irritation/ Eye burning	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
		GASTR	Nausea/ Nausea	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
		GENRL	Chills/ Chills	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
			Fatigue/ Fatigue	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
			Injection site pain/ Injection site pain	1	23OCT2020	2/3	2	Yes		NA/TC	R (25OCT2020)	N/N
			Pain/ Body pain	1	23OCT2020	2/3	2	Yes		NA/TC	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ Headache	1	23OCT2020	2/3	2	Yes		NA/TC	R (25OCT2020)	N/N
16-55/ C459100 1 1241 12412451	3	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412456	3	NERV	Headache/ Headache	1	23OCT2020	2/1	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C459100 1 1241 12412463	3	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1241 12412465	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1241 12412470	3	GENRL	Chills/ Chills	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
			Fatigue/ Fatigue	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412471	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100	3	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12412472			Pyrexia/ Fever	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
		NERV	Headache/ Headache	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412475	3	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/C	1	Yes		NA	RG	N/Y
16-55/ C459100 1 1241 12412478	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	2/5	2	Yes		NA	R (27OCT2020)	N/N
		GENRL	Chills/ Chills	1	24OCT2020	3/1	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412480	3	GENRL	Asthenia/ Asthenia	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
		NERV	Headache/ Headache	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1241 12412482	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100	3	NERV	Headache/ Headache	1	23OCT2020	1/1	1	Yes		NA/TC	R (23OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12412486		GASTR	Nausea/ Nausea	1	27OCT2020	5/1	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C459100 1 1241 12412494	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA/TC	R (24OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412498	3	NERV	Headache/ Headache	1	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412501	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412507	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412512	3	GASTR	Abdominal pain/ Abdominal pain	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
			Diarrhoea/ diarrhea	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1241 12412515	3	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412517	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/3	2	Yes		NA/TC	R (25OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	24OCT2020	2/1	2	Yes		NA/TCN	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412527	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412528	3	GENRL	Chills/ Chills	1	24OCT2020	2/3	3	Yes		NA/TC	R (26OCT2020)	N/N
			Pyrexia/ Fever	1	24OCT2020	2/3	3	Yes		NA/TC	R (26OCT2020)	N/N
		NERV	Headache/ Headache	1	24OCT2020	2/6	3	Yes		NA/TC	R (29OCT2020)	N/N
		VASC	Hypotension/ Hypotension	1	24OCT2020	2/6	3	Yes		NA/TC	R (29OCT2020)	N/N
16-55/ C459100 1 1241 12412529	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/4	2	Yes		NA	R (26OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Fatigue/ Fatigue	1	24OCT2020	2/1	2	Yes		NA/TCN	R (24OCT2020)	N/N
		NERV	Somnolence/ Somnolence	1	24OCT2020	2/1	2	Yes		NA/TCN	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412530	3	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 1 1241 12412537	3	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C459100 1 1241 12412543	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412544	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA/TCN	R (24OCT2020)	N/N
16-55/ C459100 1 1241 12412548	3	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C459100 1 1241 12412554	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C459100	3	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12412556	3	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
1 1241 12412557	3	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
1 1241 12412560	3	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N
1 1241 12412564	3	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/C	1	Yes		NA	RG	N/Y
1 1247 12471215	3	INFEC	Nasopharyngitis/ Common Cold*		07OCT2020	-5/3	1	No	O	NA	R (09OCT2020)	N/N
1 1251 12511239	3	GENRL	Chest pain/ Chest Pain	1	2020	1/	3	No	O	NA/TC	R (30OCT2020)	N/N
1 1251 12511245	3	GENRL	Injection site pain/ pain at injection site left arm	1	15OCT2020	1/4	1	Yes		NA/TC	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541185	3	GENRL	Pain/ Bodyaches	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
			Pyrexia/ Fever	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
		NERV	Headache/ Headaches	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
		EYE	Vitreous floaters/ vision changes eye floaters right eye	1	17OCT2020	4/20	1	No	O	NA	R (05NOV2020)	N/N
		NERV	Headache/ headache	1	18OCT2020	5/17	2	No	O	NA	R (03NOV2020)	N/N
16-55/ C459100 1 1254 12541187	3	GASTR	Abdominal pain lower/ right lower quadrant pain	1	02NOV2020	20/5	1	No	O	NA	R (06NOV2020)	N/N
		GENRL	Fatigue/ fatigue	1	17OCT2020	3/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C459100 1 1254 12541188	3	NERV	Headache/ intermittent headaches	2	05NOV2020	1/4	1	Yes		NA	R (08NOV2020)	N/N
		GENRL	Fatigue/ fatigue	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C459100 1 1254 12541194	3	NERV	Headache/ mild headache	1	17OCT2020	1/3	1	Yes		NA	R (19OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 1 1254 12541199	3	GENRL	Fatigue/ fatigue	1	18OCT2020	2/2	1	Yes		NA	R (19OCT2020)	N/N
		PSYCH	Anxiety/ worsening of anxiety	1	18OCT2020	2/2	1	Yes		NA	R (19OCT2020)	N/N
		SKIN	Pruritus/ body itch	1	18OCT2020	2/2	1	No	O	NA/TCN	R (19OCT2020)	N/N
		GENRL	Injection site pain/ pain at injection site	1	21OCT2020	1/18	1	Yes		NA	R (07NOV2020)	N/N
		NERV	Headache/ headache	1	21OCT2020	1/18	1	Yes		NA/TC	R (07NOV2020)	N/N
		MUSC	Myalgia/ generalized muscle aches	1	23OCT2020	3/16	1	Yes		NA	R (07NOV2020)	N/N
		GENRL	Injection site pain/ soreness at injection site	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C459100 1 1254 12541201	3	GENRL	Injection site pain/ injection site soreness	1	24OCT2020	1/3	1	Yes		NA	R (26OCT2020)	N/N
METAB		Hyperlipidaemia/ worsening hyperlipidemia	1	26OCT2020	3/C	2	No	O	NA/TC	N	N/N	
16-55/ C459100 1 1264 12641210	3	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C459100 11264 12641215	3	GENRL	Injection site pain/ Pain at injection site	1	22OCT2020	2/C	1	Yes		NA	RG	N/N
16-55/ C459100 11264 12641221	3	UNC	INJECTION SITE PAIN@@/ Injection site pain	1	23OCT2020	1/4	1	Yes		NA	R (26OCT2020)	N/N
			NECK PAIN@@/ Neck pain	1	23OCT2020	1/4	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C459100 11264 12641227	3	UNC	INJECTION SITE PAIN@@/ Injection site pain	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
18-55/ C459100 11001 10011004	1	GENRL	Malaise/ malaise	1	05MAY2020	2/1	1	No	O	NA	R (05MAY2020)	N/N
18-55/ C459100 11001 10011005	1	INJ&P	Contusion/ deltoid bruise	2	26MAY2020	1/3	1	Yes		NA	R (28MAY2020)	N/N
18-55/ C459100 11001 10011006	1	GENRL	Injection site pain/ soreness at injection site	1	07MAY2020	2/7	1	Yes		NA	R (13MAY2020)	N/N
		SKIN	Dermatitis/ dermatitis	1	09MAY2020	4/3	1	No	O	NA	R (11MAY2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
18-55/ C459100 1 1001 10011007	1	SKIN	Hand dermatitis/ dermatitis right hand	1	16MAY2020	11/20	1	No	O	NA	R (04JUN2020)	N/N
			Papule/ micropapules on skin of wrist	1	16MAY2020	11/20	1	No	O	NA	R (04JUN2020)	N/N
		SKIN	Dermatitis/ bilateral arm dermatitis	2	01JUN2020	6/4	1	No	O	NA	R (04JUN2020)	N/N
		GASTR	Diarrhoea/ diarrhea	1	19MAY2020	14/1	1	No	O	NA	R (19MAY2020)	N/N
		RESP	Nasal congestion/ Nasal congestion	1	20MAY2020	15/1	1	No	O	NA	R (20MAY2020)	N/N
		IMMUN	Seasonal allergy/ Worsening Seasonal allergies	2	31MAY2020	5/6	1	No	O	NA	R (05JUN2020)	N/N
		GASTR	Abdominal pain lower/ LLQ abdominal pain	2	06JUN2020	11/8	1	No	O	NA	R (13JUN2020)	N/N
18-55/ C459100 1 1001 10011009	1	CARD	Tachycardia/ mild tachycardia	1	07MAY2020	2/2	1	Yes		NA	R (08MAY2020)	N/N
18-55/ C459100 1 1001 10011011	1	GENRL	Injection site pain/ tenderness at left arm injection site	1	11MAY2020	1/3	1	Yes		NA	R (13MAY2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
18-55/ C459100 1 1001 10011012	1	GENRL	Pyrexia/ fever	1	17MAY2020	7/2	1	Yes		NA	R (18MAY2020)	N/N
		NERV	Presyncope/ Vaso-vagal reaction with phlebotomy*		13MAY2020	1/1	2	No	O	NA	R (13MAY2020)	N/N
		CARD	Tachycardia/ tachycardia	1	14MAY2020	2/6	1	Yes		NA	R (19MAY2020)	N/N
18-55/ C459100 1 1001 10011015	1	CARD	Tachycardia/ tachycardia	1	12MAY2020	2/7	1	Yes		NA	R (18MAY2020)	N/N
		GENRL	Fatigue/ Fatigue	1	12MAY2020	2/1	1	Yes		NA	R (12MAY2020)	N/N
			Injection site swelling/ injection site swelling at injection site	1	12MAY2020	2/2	1	Yes		NA	R (13MAY2020)	N/N
		METAB	Decreased appetite/ anorexia	2	01JUN2020	1/15	1	Yes		NA	R (15JUN2020)	N/N
		GASTR	Diarrhoea/ diarrhea	2	02JUN2020	2/2	1	Yes		NA	R (03JUN2020)	N/N
		GENRL	Chills/ Chills	2	02JUN2020	2/2	2	Yes		NA	R (03JUN2020)	N/N
		GENRL	Fatigue/ fatigue	2	02JUN2020	2/2	1	Yes		NA	R (03JUN2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
18-55/ C459100 1 1001 10011017	1	PSYCH	Pyrexia/ Fever (102.4F)	2	02JUN2020	2/2	3	Yes		NA/TC	R (03JUN2020)	N/N	
			NERV	Headache/ Headache	2	02JUN2020	2/4	2	Yes		NA/TC	R (05JUN2020)	N/N
			INSOMNIA	Insomnia/ insomnia	1	13MAY2020	1/2	2	Yes		NA	R (14MAY2020)	N/N
			MUSC	Arthralgia/ Joint pain	1	14MAY2020	2/2	1	Yes		NA	R (15MAY2020)	N/N
			MUSC	Myalgia/ muscle soreness	1	14MAY2020	2/2	1	Yes		NA	R (15MAY2020)	N/N
18-55/ C459100 1 1001 10011019	1	GASTR	Nausea/ nausea	1	14MAY2020	2/1	1	Yes		NA	R (14MAY2020)	N/N	
		PSYCH	Sleep disorder/ sleep disturbance	2	04JUN2020	2/1	1	Yes		NA	R (04JUN2020)	N/N	
18-55/ C459100 1 1001 10011021	1	GASTR	Paraesthesia oral/ Tingling sensation of mouth	1	20MAY2020	1/1	1	Yes		NA	R (20MAY2020)	N/N	
		RESP	Pharyngeal paraesthesia/ Tingling sensation of throat	1	20MAY2020	1/1	1	Yes		NA	R (20MAY2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
18-55/ C459100 1 1001 10011024	1	MUSC	Arthralgia/ shoulder pain	1	13MAY2020	1/2	2	Yes		NA	R (14MAY2020)	N/N
			Back pain/ back pain	1	13MAY2020	1/2	2	Yes		NA	R (14MAY2020)	N/N
18-55/ C459100 1 1001 10011026	1	CARD	Tachycardia/ tachycardia	1	18MAY2020	1/2	1	Yes		NA	R (19MAY2020)	N/N
18-55/ C459100 1 1001 10011028	1	PSYCH	Sleep disorder/ Sleep disturbance	1	20MAY2020	1/4	2	Yes		NA	R (23MAY2020)	N/N
		MUSC	Pain in extremity/ Left plantar heel pain	1	16JUL2020	58/13	2	No	O	NA/TCN	R (28JUL2020)	N/N
		GASTR	Nausea/ nausea	2	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
		RESP	Oropharyngeal pain/ Intermittent sore throat	2	03NOV2020	79/C	1	No	O	NA	N	N/N
18-55/ C459100 1 1001 10011030	1	PSYCH	Sleep disorder/ Moderate sleep disturbance	1	20MAY2020	1/9	2	Yes		NA	R (28MAY2020)	N/N
		GENRL	Injection site pain/ Injection site pain	1	21MAY2020	2/4	1	Yes		NA	R (24MAY2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ muscle pain	1	21MAY2020	2/2	1	Yes		NA	R (22MAY2020)	N/N
18-55/ C459100 1 1001 10011032	1	GENRL	Injection site erythema/ Injection site redness	1	24MAY2020	5/2	1	Yes		NA	R (25MAY2020)	N/N
18-55/ C459100 1 1001 10011034	1	NERV	Presyncope/ Vaso-vagal reaction with finger prick*		15MAY2020	-5/1	2	No	O	NA	R (15MAY2020)	N/N
		GASTR	Nausea/ nausea	1	20MAY2020	1/6	2	Yes		NA	R (25MAY2020)	N/N
		PSYCH	Sleep disorder/ sleep disturbance	1	20MAY2020	1/3	3	Yes		NA	R (22MAY2020)	N/N
		METAB	Decreased appetite/ loss of appetite	1	21MAY2020	2/24	2	Yes		NA	R (13JUN2020)	N/N
		NERV	Presyncope/ vasovagal reaction	1	09JUL2020	51/1	2	No	O	NA	R (09JUL2020)	N/N
		GENRL	Fatigue/ fatigue	2	17AUG2020	1/9	1	Yes		NA	R (25AUG2020)	N/N
		GASTR	Nausea/ nausea	2	24AUG2020	8/1	1	No	O	NA	R (24AUG2020)	N/N
18-55/ C459100 1 1001 10011068	1	GASTR	Nausea/ Nausea	1	30JUN2020	2/1	1	Yes		NA/TC	R (30JUN2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
18-55/ C459100 1 1001 10011069	1	NERV	Paraesthesia/ Left lower extremity tingling	1	02JUL2020	4/3	1	No	O	NA	R (04JUL2020)	N/N
		NERV	Neuropathy peripheral/ Bilateral lower extremity neuropathy	2	20JUL2020	1/18	1	No	O	NA	R (06AUG2020)	N/N
		EYE	Retinal tear/ retinal eye tear	2	29JUL2020	10/2	2	No	O	NA	R (30JUL2020)	N/N
		NERV	Neuropathy peripheral/ neuropathy in right arm	2	30JUL2020	11/8	1	No	O	NA	R (06AUG2020)	N/N
		SKIN	Rash/ Rash	1	18JUL2020	18/4	1	No	O	NA	R (21JUL2020)	N/N
		NERV	Disturbance in attention/ difficulty concentrating post vaccination	1	01JUL2020	1/2	1	Yes		NA	R (02JUL2020)	N/N
		NERV	Paraesthesia/ Tingling LE BIL	1	01JUL2020	1/1	1	Yes		NA	R (01JUL2020)	N/Y
		NERV	Dizziness/ lightheadedness	1	09JUL2020	9/1	1	No	O	NA	R (09JUL2020)	N/N
		PSYCH	Sleep disorder/ sleep disturbance post vaccination	1	01JUL2020	1/2	1	No	O	NA	R (02JUL2020)	N/N
18-55/ C459100 1 1001 10011076	1	GENRL	Injection site pain/ injection site tenderness	1	02JUL2020	2/3	1	Yes		NA	R (04JUL2020)	N/N
		SKIN	Rash/ Upper Extremity Rash	1	05JUL2020	5/11	1	No	O	NA	R (15JUL2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
18-55/ C459100 1 1002 10021011	1	NERV	Headache/ headache	2	22JUL2020	2/2	1	Yes		NA	R (23JUL2020)	N/N
		GASTR	Abdominal discomfort/ upset stomach	2	25JUL2020	5/3	1	No	O	NA/TC	R (27JUL2020)	N/N
			Diarrhoea/ Loose stools	2	25JUL2020	5/2	1	Yes		NA/TC	R (26JUL2020)	N/N
18-55/ C459100 1 1002 10021023	1	RESP	Cough/ Cough	1	08MAY2020	3/3	1	Yes		NA	R (10MAY2020)	N/N
		RESP	Dyspnoea/ Shortness of Breath	2	15JUN2020	21/13	1	No	O	NA	R (27JUN2020)	N/N
			Throat irritation/ Throat Irritation	2	15JUN2020	21/13	1	No	O	NA	R (27JUN2020)	N/N
18-55/ C459100 1 1002 10021024	1	INFEC	Hordeolum/ Stye right lower eyelid	1	13AUG2020	88/8	1	No	O	NA/TC	R (20AUG2020)	N/N
18-55/ C459100 1 1002 10021024	1	GASTR	Nausea/ Nausea	1	18MAY2020	1/3	2	Yes		NA	R (20MAY2020)	N/N
		INFEC	Urinary tract infection/ Urinary Tract Infection	1	21MAY2020	4/11	1	No	O	NA/TC	R (31MAY2020)	N/N
		INJ&P	Wound/ Shoulder Wound	1	25JUN2020	39/13	1	No	O	NA/TC	R (07JUL2020)	N/N
		GASTR	Nausea/ Nausea	2	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
18-55/ C459100 1 1002 10021036	1	GENRL	Fatigue/ Fatigue	1	16JUN2020	27/13	1	No	O	NA/TC	R (28JUN2020)	N/N
		RESP	Sinus congestion/ Sinus Fullness	1	16JUN2020	27/11	1	No	O	NA	R (26JUN2020)	N/N
		INFEC	Wound infection/ Multiple wound infection	2	23AUG2020	6/9	1	No	O	NA/TC	R (31AUG2020)	N/N
		INJ&P	Fall/ Fall	2	23AUG2020	6/1	1	No	O	NA	R (23AUG2020)	N/N
18-55/ C459100 1 1002 10021080	1	INJ&P	Muscle strain/ Muscle Strain middle back	1	04JUL2020	4/11	1	No	O	NA	R (14JUL2020)	N/N
		NERV	Paraesthesia/ Tingling in both hands	2	21JUL2020	1/1	1	Yes		NA	R (21JUL2020)	N/N
18-55/ C459100 1 1002 10021082	1	INJ&P	Muscle strain/ Neck Strain	2	24JUL2020	4/3	1	No	O	NA/TC	R (26JUL2020)	N/N
18-55/ C459100 1 1003 10031020	1	MUSC	Muscle spasms/ worsening leg cramps left calf	2	10JUL2020	9/5	2	No	O	NA	R (14JUL2020)	N/N
18-55/ C459100 1 1003 10031030	1	INJ&P	Ligament sprain/ Right sprained ankle	2	06AUG2020	30/75	1	No	O	NA	R (19OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
18-55/ C459100 1 1003 10031065	1	MUSC	Pain in extremity/ right arm pain	2	29JUL2020	15/C	2	No	O	NA	N	N/N
		NERV	Neuritis/ neuritis right arm	2	29JUL2020	15/C	3	No	O	NA	N	Y/N
18-55/ C459100 1 1003 10031066	1	INJ&P	Fall/ fall while exercising	1	24JUN2020	3/1	2	No	O	NA/TCN	R (24JUN2020)	N/N
			Tendon injury/ Achilles tendon injury	1	24JUN2020	3/7	2	No	O	NA/TCN	R (30JUN2020)	N/N
18-55/ C459100 1 1007 10071014	1	MUSC	Myalgia/ LEFT SHOULDER MUSCLE PAIN	1	18JUN2020	8/16	2	No	O	NA/TC	R (03JUL2020)	N/N
			Myalgia/ Left Scapula area muscle pain	1	18JUN2020	8/16	2	No	O	NA/TC	R (03JUL2020)	N/N
		INFEC	Urinary tract infection/ Urinary Tract Infection	1	27JUN2020	17/11	1	No	O	NA/TC	R (07JUL2020)	N/N
	RENAL	Nephrolithiasis/ renal calculi	1	27JUN2020	17/23	2	No	O	NA/TC/TCN	R (19JUL2020)	N/N	
18-55/ C459100 1 1007 10071017	1	GENRL	Injection site pain/ left injection site arm pain	1	15JUN2020	1/3	1	Yes		NA	R (17JUN2020)	N/N
18-55/ C459100	1	GENRL	Injection site pain/ tenderness at injection site	1	08JUN2020	1/1	1	Yes		NA	R (08JUN2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1007 10071019		RESP	Rhinorrhoea/ nasal drainage	2	03JUL2020	5/8	1	No	O	NA/TC	R (10JUL2020)	N/N
18-55/ C459100 1 1007 10071020	1	GENRL	Injection site erythema/ redness at injection site	1	10JUN2020	1/1	1	Yes		NA	R (10JUN2020)	N/N
18-55/ C459100 1 1007 10071021	1	GENRL	Injection site erythema/ redness at injection site	1	10JUN2020	1/1	1	Yes		NA	R (10JUN2020)	N/Y
18-55/ C459100 1 1007 10071025	1	GASTR	Oral disorder/ oral lesion	1	29JUN2020	13/12	1	No	O	NA/TC	R (10JUL2020)	N/N
18-55/ C459100 1 1007 10071026	1	SKIN	Rash papular/ erythematous papular rash chest, forehead, cheek	2	12JUL2020	7/7	1	Yes		NA/TC	R (18JUL2020)	N/N
18-55/ C459100 1 1007 10071027	1	PSYCH	Sleep disorder/ Sleep disturbance	1	17JUN2020	1/4	1	Yes		NA	R (20JUN2020)	N/N
18-55/ C459100 1 1007 10071029	1	NERV	Ageusia/ partial loss of taste	1	17JUN2020	1/1	1	Yes		NA	R (17JUN2020)	N/Y

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Taste disorder/ change in sensation of taste	2	08JUL2020	1/2	1	Yes		NA	R (09JUL2020)	N/Y
18-55/ C459100 1 1007 10071046	1	NERV	Migraine/ Migraine Exacerbation	1	28JUN2020	7/2	3	No	O	NA	R (29JUN2020)	N/N
18-55/ C459100 1 1007 10071050	1	BLOOD	Lymphadenopathy/ Right axillary lymph node enlargement	2	15JUL2020	3/13	1	Yes		NA	R (27JUL2020)	N/N
18-55/ C459100 1 1007 10071063	1	GENRL	Injection site pain/ soreness at injection site	1	24JUN2020	1/1	1	Yes		NA	R (24JUN2020)	N/Y
18-55/ C459100 1 1007 10071066	1	NERV	Dizziness/ Dizziness	2	16JUL2020	2/1	2	Yes		NA/TCN	R (16JUL2020)	N/N
65-85/ C459100 1 1001 10011037	1	EYE	Eye paraesthesia/ intermittent paraesthesia in both eyes	1	11JUN2020	1/2	1	Yes		NA/TC	R (12JUN2020)	N/Y
		NERV	Headache/ intermittent headache	2	01JUL2020	2/C	1	No	O	NA	N	N/N
65-85/ C459100 1 1001 10011039	1	MUSC	Muscle spasms/ worsening leg cramps	1	14JUN2020	6/2	2	No	O	NA	R (15JUN2020)	N/N
		GENRL	Fatigue/ fatigue	2	29JUN2020	1/3	1	Yes		NA	R (01JUL2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
65-85/ C459100 1 1001 10011040	1	GASTR	Aphthous ulcer/ aphthous ulcer	2	04JUL2020	6/4	1	Yes		NA	R (07JUL2020)	N/N
		MUSC	Back pain/ Low back pain	2	07AUG2020	40/C	2	No	CND	NA	N	N/N
		GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux	2	01AUG2020	31/26	1	No	O	NA/TC	R (26AUG2020)	N/N
		RESP	Oropharyngeal pain/ sore throat	2	01AUG2020	31/26	1	No	O	NA	R (26AUG2020)	N/N
65-85/ C459100 1 1001 10011041	1	MUSC	Arthralgia/ Joint pain	2	27AUG2020	57/C	1	No	O	NA/TC	RG	N/N
		MUSC	Myalgia/ Muscle pain	2	27AUG2020	57/C	1	No	O	NA/TC	RG	N/N
65-85/ C459100 1 1001 10011042	1	MUSC	Myalgia/ muscle pain	1	12JUN2020	2/2	1	Yes		NA	R (13JUN2020)	N/N
		SKIN	Dermatitis contact/ contact dermatitis	1	12JUN2020	2/2	1	No	O	NA	R (13JUN2020)	N/N
65-85/ C459100 1 1001 10011043	1	NERV	Dizziness/ Lightheadedness	2	14JUL2020	7/1	1	No	O	NA	R (14JUL2020)	N/N
65-85/ C459100	1	SKIN	Ecchymosis/ echymosis to left deltoid	2	16JUL2020	15/9	1	No	O	NA	R (24JUL2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1001 10011045	1	INJ&P	Skin abrasion/ excoriation palms, BIL	2	13JUL2020	5/25	1	No	O	NA	R (06AUG2020)	N/N
1 1001 10011046			Skin abrasion/ excoriation right elbow	2	13JUL2020	5/25	1	No	O	NA	R (06AUG2020)	N/N
		MUSC	Pain in extremity/ right thigh pain	2	13JUL2020	5/25	1	No	O	NA	R (06AUG2020)	N/N
		INJ&P	Contusion/ right knee bruise	2	16JUL2020	8/22	1	No	O	NA/TCN	R (06AUG2020)	N/N
			Fall/ fall	2	16JUL2020	8/1	1	No	O	NA	R (16JUL2020)	N/N
			Road traffic accident/ bike accident	2	16JUL2020	8/1	1	No	O	NA	R (16JUL2020)	N/N
		GENRL	Oedema peripheral/ right thigh edema	2	22JUL2020	14/16	1	No	O	NA	R (06AUG2020)	N/N
65-85/ C459100	1	GENRL	Injection site bruising/ injection site bruising	1	16JUN2020	1/15	1	Yes		NA	R (30JUN2020)	N/N
1 1001 10011048		SKIN	Dermatitis contact/ contact dermatitis	1	16JUN2020	1/4	1	No	O	NA	R (19JUN2020)	N/N
		GASTR	Abdominal discomfort/ Abdominal Discomfort	2	09JUL2020	2/2	1	Yes		NA	R (10JUL2020)	N/N
		METAB	Decreased appetite/ Anorexia	2	09JUL2020	2/3	1	Yes		NA	R (11JUL2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		PSYCH	Irritability/ Irritability	2	09JUL2020	2/3	1	Yes		NA	R (11JUL2020)	N/N
65-85/ C459100 1 1001 10011049	1	GENRL	Fatigue/ intermittent fatigue	2	13JUL2020	8/C	1	Yes		NA	RG	N/N
65-85/ C459100 1 1001 10011052	1	BLOOD	Anaemia/ Anemia	1	08JUL2020	22/C	2	No	O	NA	RG	N/N
65-85/ C459100 1 1001 10011053	1	MUSC	Arthralgia/ Right Shoulder Pain	1	01JUL2020	16/C	2	No	O	NA	N	N/N
65-85/ C459100 1 1001 10011055	1	PSYCH	Sleep disorder/ sleep disturbance	1	18JUN2020	2/1	1	Yes		NA	R (18JUN2020)	N/N
		METAB	Decreased appetite/ Anorexia	2	09JUL2020	2/4	1	Yes		NA	R (12JUL2020)	N/N
65-85/ C459100 1 1001 10011057	1	INJ&P	Venomous sting/ Jellyfish sting	2	19JUL2020	12/1	1	No	O	NA	R (19JUL2020)	N/N
65-85/ C459100 1 1001 10011058	1	SKIN	Ecchymosis/ ecchymosis left arm*		16JUN2020	-2/4	1	No	O	NA	R (19JUN2020)	N/N
65-85/ C459100	1	GENRL	Injection site pain/ injection site tenderness	1	18JUN2020	2/3	1	Yes		NA	R (20JUN2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1001 10011059		INJ&P	Fall/ Fall	1	03JUL2020	17/1	1	No	O	NA	R (03JUL2020)	N/N
			Fibula fracture/ proximal non-displaced fracture of the right fibula	1	03JUL2020	17/5	2	No	O	NA	R (07JUL2020)	N/N
65-85/ C459100 1 1001 10011063	1	MUSC	Myalgia/ Left deltoid local site pain	1	18JUN2020	1/3	1	Yes		NA	R (20JUN2020)	N/N
		GENRL	Fatigue/ Fatigue	2	07JUL2020	1/2	3	Yes		NA/TC	R (08JUL2020)	N/N
			Peripheral swelling/ Swelling on left arm 4x2cm	2	07JUL2020	1/16	1	Yes		NA	R (22JUL2020)	N/N
65-85/ C459100 1 1002 10021043	1	INJ&P	Skin laceration/ Laceration Right Thumb	1	10JUN2020	2/13	2	No	O	NA	R (22JUN2020)	N/N
		SURG	Suture insertion/ Right Thumb Suture Insertion	1	10JUN2020	2/13	2	No	O	NA	R (22JUN2020)	N/N
65-85/ C459100 1 1002 10021044	1	SKIN	Hyperhidrosis/ Sweating	1	10JUN2020	2/1	1	Yes		NA	R (10JUN2020)	N/N
		RESP	Dyspnoea/ Shortness of Breath	1	12JUN2020	4/1	1	No	O	NA	R (12JUN2020)	N/N
65-85/ C459100	1	RESP	Oropharyngeal pain/ Sore Throat	1	16JUN2020	2/1	1	No	O	NA	R (16JUN2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1002 10021050 65-85/ C459100	1	MUSC	Back pain/ Lower back pain	1	27JUN2020	17/3	1	No	O	NA/TC	R (29JUN2020)	N/N
1 1002 10021052 65-85/ C459100	1	INFEC	Herpes zoster/ Shingles	1	16JUN2020	2/3	3	No	O	NA/TC	R (18JUN2020)	N/N
1 1002 10021060		GASTR	Toothache/ Tooth Pain	2	13JUL2020	7/2	1	No	O	NA/TC	R (14JUL2020)	N/N
		SURG	Tooth extraction/ Tooth Extraction	2	13JUL2020	7/1	1	No	O	NA/TC	R (13JUL2020)	N/N
65-85/ C459100 1 1002 10021071	1	GASTR	Nausea/ Nausea	2	09JUL2020	2/1	2	Yes		NA	R (09JUL2020)	N/N
65-85/ C459100 1 1003 10031035	1	NERV	Presyncope/ near syncope	2	06AUG2020	32/1	1	No	O	NA	R (06AUG2020)	N/N
65-85/ C459100 1 1003 10031058	1	MUSC	Muscle spasms/ Worsening leg cramping	2	10JUL2020	2/5	3	No	O	NA	R (14JUL2020)	N/N
65-85/ C459100	1	NERV	Radiculopathy/ worsening radiculitis	1	03JUL2020	3/6	3	No	O	NA	R (08JUL2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1003 10031083 65-85/ C459100	1	NERV	Sciatica/ exacerbation of sciatica	1	22JUN2020	5/26	1	No	O	NA/TC/TCN	R (17JUL2020)	N/N
1 1007 10071043 65-85/ C459100	1	VASC	Hypertension/ Hypertension	2	13JUL2020	5/C	2	No	O	NA/TC	N	N/N
1 1007 10071049 65-85/ C459100	1	GASTR	Nausea/ nausea	1	18JUN2020	2/2	2	Yes		NA	R (19JUN2020)	N/N
1 1007 10071052 65-85/ C459100	1	GASTR	Nausea/ Nausea	1	22JUN2020	6/2	1	Yes		NA	R (23JUN2020)	N/N
1 1007 10071071 65-85/ C459100	1	INJ&P	Contusion/ coccyx contusion	1	04JUL2020	6/18	1	No	O	NA	R (21JUL2020)	N/N
			Contusion/ right knee contusion	1	04JUL2020	6/42	1	No	O	NA	R (14AUG2020)	N/N
			Fall/ fall from side of bathtub	1	04JUL2020	6/1	1	No	O	NA	R (04JUL2020)	N/N
65-85/ C459100 1 1007 10071075	1	SURG	Tooth extraction/ Tooth extraction	1	12JUL2020	13/1	2	No	O	NA/TC	R (12JUL2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		SURG	Tooth extraction/ tooth extraction	1	14JUL2020	15/1	2	No	O	NA/TCN	R (14JUL2020)	N/N
>55/ C459100 1 1005 10051247	3	MUSC	Back pain/ BACK PAIN	1	16OCT2020	4/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1005 10051262	3	MUSC	Neck pain/ NECK ACHE	1	15OCT2020	1/4	1	Yes		NA	R (18OCT2020)	N/N
>55/ C459100 1 1005 10051263	3	GENRL	Chills/ CHILLS	2	05NOV2020	1/2	2	Yes		NA	R (06NOV2020)	N/N
			Fatigue/ FATIGUE	2	05NOV2020	1/5	2	Yes		NA	R (09NOV2020)	N/N
		MUSC	Myalgia/ MYALGIA	2	05NOV2020	1/5	2	Yes		NA/TC	R (09NOV2020)	N/N
>55/ C459100 1 1005 10051265	3	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	15OCT2020	1/4	1	Yes		NA	R (18OCT2020)	N/N
		METAB	Decreased appetite/ LOSS OF APPETITE	1	15OCT2020	1/C	1	Yes		NA	N	N/N
>55/ C459100 1 1005 10051272	3	GENRL	Chills/ CHILLS	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1005 10051275	3	GENRL	Fatigue/ FATIGUE	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N
			Myalgia/ MYALGIA	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N
			Malaise/ MALAISE	1	18OCT2020	4/3	2	Yes		NA	R (20OCT2020)	N/N
>55/ C459100 1 1005 10051282	3	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 1005 10051293	3	CARD	Cardiac arrest/ CARDIAC ARREST	1	08NOV2020	21/1	4	No	O	NA/TC	R (08NOV2020)	Y/N
		INJ&P	Overdose/ Overdose	1	08NOV2020	21/1	4	No	O	NA	R (08NOV2020)	Y/N
		RESP	Acute respiratory failure/ Acute Respiratory Failure	1	08NOV2020	21/C	4	No	O	NA	RG	Y/N
>55/ C459100 1 1005 10051304	3	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
>55/ C459100 1 1005 10051320	3	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	21OCT2020	2/20	1	Yes		NA	R (09NOV2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1005 10051336	3	PSYCH	Libido decreased/ LOW LIBIDO	1	06NOV2020	17/C	1	No	O	NA	N	N/N
>55/ C459100 1 1005 10051355	3	GENRL	Injection site pain/ TENDERNESS AT INJECTION SITE	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
>55/ C459100 1 1005 10051374	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	26OCT2020	1/3	2	Yes		NA	R (28OCT2020)	N/N
		NERV	Headache/ HEADACHE	1	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N
>55/ C459100 1 1005 10051403	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04NOV2020	1/4	2	Yes		NA/TC	R (07NOV2020)	N/N
>55/ C459100 1 1006 10061177	3	GENRL	Injection site pain/ Injection Site Pain	1	21OCT2020	1/5	1	Yes		NA	R (25OCT2020)	N/N
>55/ C459100 1 1007 10071298	3	GENRL	Injection site paraesthesia/ Tingling at injection site	1	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/Y
>55/ C459100 1 1007 10071301	3	GENRL	Injection site pain/ injection site pain	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1007 10071310	3	GENRL	Fatigue/ fatigue	1	14OCT2020	3/3	1	Yes		NA	RS (16OCT2020)	N/N
		MUSC	Myalgia/ bilateral hand myalgia	1	14OCT2020	3/C	1	Yes		NA	RG	N/N
		GENRL	Injection site pain/ injection site tenderness	2	03NOV2020	2/C	1	Yes		NA	RG	N/N
			Pyrexia/ fever	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
		PSYCH	Insomnia/ insomnia	2	03NOV2020	2/C	2	Yes		NA	RG	N/N
>55/ C459100 1 1007 10071314	3	GENRL	Injection site pain/ Injection site pain	1	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N
>55/ C459100 1 1007 10071315	3	EAR	Deafness/ hearing loss	1	01NOV2020	20/C	2	No	O	NA/TC	N	N/N
>55/ C459100 1 1007 10071319	3	RESP	Cough/ Coughing	1	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N
>55/ C459100 1 1007 10071320	3	MUSC	Pain in extremity/ left arm soreness	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1007 10071321	3	GENRL	Injection site erythema/ Injection site erythema	2	03NOV2020	1/C	1	Yes		NA	RG	N/N
			Injection site induration/ Injection site induration	2	03NOV2020	1/C	1	Yes		NA	RG	N/N
			Injection site pain/ Injection site tenderness	2	03NOV2020	1/C	1	Yes		NA	RG	N/N
>55/ C459100 1 1007 10071322	3	GENRL	Injection site pain/ Tenderness at injection site	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
			Injection site swelling/ swelling at injection site	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 1007 10071333	3	GENRL	Injection site erythema/ Erythema at injection site	1	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
			Injection site pain/ Pain at injection site	1	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
			Fatigue/ Fatigue	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Malaise/ Malaise	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
			Chills/ Chills	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
			GASTR	Diarrhoea/ Diarrhea	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1007 10071347	3	METAB	Decreased appetite/ Loss of appetite	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
		MUSC	Myalgia/ Myalgia	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
		CARD	Atrial fibrillation/ atrial fibrillation	1	25OCT2020	11/2	3	No	O	NA/TC	R (26OCT2020)	Y/N
>55/ C459100 1 1007 10071354	3	GENRL	Injection site induration/ Induration at injection site	1	15OCT2020	1/C	1	Yes		NA	RG	N/Y
>55/ C459100 1 1007 10071355	3	GENRL	Injection site pain/ tenderness at injection site	1	15OCT2020	1/C	2	Yes		NA	RG	N/Y
>55/ C459100 1 1007 10071379	3	GENRL	Injection site pain/ pain extending from injection site to elbow	1	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N
>55/ C459100 1 1007 10071384	3	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
		GENRL	Chills/ Chills	2	11NOV2020	2/1	2	Yes		NA/TC	R (11NOV2020)	N/N
			Injection site pain/ Injection site pain	2	11NOV2020	2/C	2	Yes		NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ Fever	2	11NOV2020	2/1	2	Yes		NA/TC	R (11NOV2020)	N/N
		NERV	Headache/ Headache	2	11NOV2020	2/1	2	Yes		NA/TC	R (11NOV2020)	N/N
		GENRL	Chills/ Chills	2	12NOV2020	3/C	2	Yes		NA/TC	RG	N/N
			Pyrexia/ Fever	2	12NOV2020	3/C	2	Yes		NA/TC	RG	N/N
		MUSC	Myalgia/ Myalgia	2	12NOV2020	3/C	2	Yes		NA/TC	RG	N/N
>55/ C459100 1 1007 10071412	3	GENRL	Chills/ Chills	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
>55/ C459100 1 1007 10071430	3	GENRL	Injection site pain/ Achiness at injection site	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/Y
>55/ C459100 1 1007 10071432	3	GENRL	Injection site pain/ Soreness at injection site	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
			Injection site swelling/ Swelling at injection site	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		INFEC	Urinary tract infection/ urinary tract infection	1	06NOV2020	12/C	2	No	O	NA	RG	N/N
>55/ C459100	3	GENRL	Injection site pain/ Injection site pain	1	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1008 10081586 >55/ C459100 1 1008 10081602	3	GENRL	Fatigue/ Fatigue	2	04NOV2020	1/2	2	Yes		NA	R (05NOV2020)	N/N
			Pain/ Body aches	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N
			Pyrexia/ Fever	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N
>55/ C459100 1 1008 10081603	3	INFECTION	Cellulitis/ CELLULITIS UPPER BACK	1	26OCT2020	13/8	3	No	O	NA/TC	R (02NOV2020)	Y/N
			Sepsis/ SEPSIS	1	26OCT2020	13/8	3	No	O	NA/TC	R (02NOV2020)	Y/N
			Subcutaneous abscess/ SCALP ABCESS	1	26OCT2020	13/C	3	No	O	NA/TC/TCN	N	N/N
>55/ C459100 1 1008 10081610	3	GENRL	Chills/ Chills	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
			Pain/ Body aches	2	04NOV2020	2/1	2	Yes		NA/TC	R (04NOV2020)	N/N
			Pyrexia/ Fever	2	04NOV2020	2/1	1	Yes		NA/TC	R (04NOV2020)	N/N
>55/ C459100	3	GENRL	Chills/ Chills	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1008 10081622			Pain/ Body aches	2	07NOV2020	2/1	1	Yes		NA/TC	R (07NOV2020)	N/N
>55/ C459100 1 1008 10081645	3	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
>55/ C459100 1 1008 10081656	3	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
			Injection site pain/ Injection site pain	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
		NERV	Headache/ Headache	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
>55/ C459100 1 1008 10081660	3	INJ&P	Tooth fracture/ Cracked left lower molar	1	07NOV2020	18/3	1	No	O	NA/TC/TCN	R (09NOV2020)	N/N
>55/ C459100 1 1008 10081724	3	GENRL	Injection site pain/ Injection site pain	1	29OCT2020	1/C	1	Yes		NA	N	N/N
>55/ C459100	3	INV	Body temperature increased/ Increased Body Temperature (99.8F)	2	03NOV2020	1/2	1	Yes		NA/TC	R (04NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1011 10111188		MUSC	Myalgia/ Generalized Muscle Aches	2	03NOV2020	1/2	1	Yes		NA/TC	R (04NOV2020)	N/N
>55/ C459100 1 1011 10111201	3	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
			Pyrexia/ Fever 101.0	2	06NOV2020	2/2	2	Yes		NA	R (07NOV2020)	N/N
		METAB	Decreased appetite/ Loss of Appetite	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
>55/ C459100 1 1011 10111218	3	NERV	Headache/ Headache	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
>55/ C459100 1 1011 10111230	3	GENRL	Injection site pain/ Soreness at injection site	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
		GENRL	Chills/ Chills	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
			Injection site pain/ Injection Site Pain	2	14NOV2020	2/1	1	Yes		NA/TC	R (14NOV2020)	N/N
			Pyrexia/ Fever (100.7)	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Generalized Muscle Aches	2	14NOV2020	2/1	1	Yes		NA/TC	R (14NOV2020)	N/N
>55/ C459100 1 1013 10131692	3	GENRL	Pyrexia/ LOW GRADE FEVER	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
>55/ C459100 1 1013 10131698	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 1013 10131707	3	GENRL	Pain/ BODY ACHES	1	15OCT2020	3/3	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 1013 10131715	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1013 10131719	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 1013 10131728	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 1013 10131741	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16OCT2020	2/3	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1013 10131743	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
		GENRL	Pain/ BODY ACHES	2	06NOV2020	2/C	1	Yes		NA	RG	N/N
			Pyrexia/ LOW GRADE FEVER	2	06NOV2020	2/C	1	Yes		NA	RG	N/N
>55/ C459100 1 1013 10131751	3	GENRL	Fatigue/ FATIGUE	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
>55/ C459100 1 1013 10131753	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
>55/ C459100 1 1013 10131754	3	GENRL	Chills/ CHILLS	2	11NOV2020	2/C	1	Yes		NA	RG	N/N
>55/ C459100 1 1013 10131814	3	GENRL	Injection site pain/ INJECTION SITE PAIN	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
>55/ C459100 1 1015 10151244	3	GENRL	Pain/ Body aches	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INJ&P	Administration related reaction/ Sore arm - whole arm that received IP	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		INV	Body temperature increased/ Increased temperature 99.2	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
		GENRL	Chills/ Chills	2	04NOV2020	1/C	2	Yes		NA/TC	RG	N/N
			Injection site pain/ Injection site soreness	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
			Pain/ Body aches	2	04NOV2020	1/C	2	Yes		NA/TC	RG	N/N
			Pyrexia/ Fever	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
>55/ C459100 1 1015 10151251	3	INJ&P	Stress fracture/ Hair line fracture of right humerus	1	07NOV2020	19/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1018 10181312	3	INJ&P	Skin laceration/ Left Elbow laceration	1	26OCT2020	15/1	2	No	O	NA	R (26OCT2020)	N/N
>55/ C459100 1 1019 10191271	3	GENRL	Injection site pain/ Injection site soreness	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 1019 10191275	3	GENRL	Injection site swelling/ Left arm swelling at injection site	2	05NOV2020	2/5	1	Yes		NA	R (09NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1019 10191302	3	GENRL	Pyrexia/ Fever (101.6F)	2	14NOV2020	2/C	1	Yes		NA	N	N/N
>55/ C459100 1 1028 10281268	3	GENRL	Fatigue/ fatigue	1	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
		NERV	Headache/ headache	1	20OCT2020	1/1	2	Yes		NA	R (20OCT2020)	N/N
		GASTR	Diarrhoea/ diarrhea	1	21OCT2020	2/2	2	Yes		NA	R (22OCT2020)	N/N
			Retching/ dry heaving	1	21OCT2020	2/2	2	Yes		NA	R (22OCT2020)	N/N
		GENRL	Chills/ chills	1	21OCT2020	2/2	2	Yes		NA	R (22OCT2020)	N/N
			Injection site pain/ left deltoid soreness (injection site)	1	21OCT2020	2/2	2	Yes		NA	R (22OCT2020)	N/N
		SKIN	Hyperhidrosis/ sweating	1	21OCT2020	2/2	2	Yes		NA	R (22OCT2020)	N/N
>55/ C459100 1 1028 10281273	3	NERV	Dizziness/ lightheaded	1	22OCT2020	1/C	2	Yes		NA	N	N/Y
>55/ C459100 1 1028 10281277	3	GENRL	Injection site pain/ pain at injection site left arm	1	23OCT2020	1/4	2	Yes		NA/TC	R (26OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1036 10361130	3	GENRL	Injection site erythema/ redness at injection site left arm	1	24OCT2020	2/3	2	Yes		NA	R (26OCT2020)	N/N
		GENRL	Injection site pain/ Pain at injection site	1	16OCT2020	1/3	2	Yes		NA/TC	R (18OCT2020)	N/Y
		GENRL	Chills/ Chills	1	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
			Fatigue/ Fatigue	1	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
			Pain/ Body Aches	1	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
			Pyrexia/ Fever	1	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
>55/ C459100 1 1037 10371334	3	GASTR	Dental caries/ DENTAL CARIES	1	02NOV2020	22/3	1	No	O	NA	R (04NOV2020)	N/N
>55/ C459100 1 1039 10391189	3	GENRL	Injection site pain/ injection site pain	1	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 1039 10391192	3	GENRL	Injection site pain/ injection site soreness	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
MUSC		Myalgia/ muscle ache, left arm	1	16OCT2020	1/1	1	Yes		NA/TC	R (16OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		GENRL	Chills/ chills	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/N
			Injection site pain/ injection site pain	2	06NOV2020	1/C	1	Yes		NA	RG	N/Y
>55/ C459100 1 1039 10391217	3	GENRL	NERV Headache/ headache	2	06NOV2020	1/1	1	Yes		NA/TC	R (06NOV2020)	N/N
			Fatigue/ fatigue	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
>55/ C459100 1 1044 10441184	3	GENRL	Injection site pain/ injection site pain	1	22OCT2020	1/2	2	Yes		NA/TC	R (23OCT2020)	N/N
			Chills/ chills	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 1044 10441194	3	GENRL	Injection site pain/ injection site pain	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
			MUSC Myalgia/ myalgia	1	18OCT2020	3/3	1	Yes		NA	R (20OCT2020)	N/N
			NERV Headache/ headache	1	18OCT2020	3/2	1	Yes		NA	R (19OCT2020)	N/N
			Injection site pain/ injection site pain	1	18OCT2020	1/2	1	Yes		NA	R (19OCT2020)	N/N
		GENRL	Injection site pain/ injection site pain	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1044 10441205	3	GENRL	Injection site pain/ injection site pain	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
>55/ C459100 1 1044 10441208	3	INV	Intraocular pressure increased/ INCREASED INTRAOCULAR PRESSURE	1	10NOV2020	21/C	1	Yes		NA/TC	RG	N/N
>55/ C459100 1 1044 10441209	3	INFEC	Vulvovaginal mycotic infection/ Vaginal yeast infection	1	22OCT2020	2/4	1	No	O	NA/TC	R (25OCT2020)	N/N
>55/ C459100 1 1044 10441220	3	EAR	Ear pain/ Right earache	1	30OCT2020	8/8	1	No	O	NA	R (06NOV2020)	N/N
>55/ C459100 1 1054 10541210	3	UNC	L ARM SITE INJECTION PAIN@@/ L arm site injection pain	1	28OCT2020	1/3	1	Yes		NA/TC	R (30OCT2020)	N/N
		UNC	FATIGUE@@/ fatigue	1	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
			L OPEN HEAVINESS@@/ L open heaviness	1	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
>55/ C459100 1 1054 10541211	3	UNC	L ARM SITE INJECTION PAIN@@/ L arm site injection pain	1	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1056 10561557	3	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE LEFT	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
>55/ C459100 1 1057 10571306	3	GENRL	Injection site pain/ Soreness at injection site on left arm	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1057 10571327	3	INFEC	Peritonsillar abscess/ PENTONSILLAR ABSESS	1	22OCT2020	7/C	3	No	O	NA/TC/TCN	N	Y/N
>55/ C459100 1 1066 10661318	3	GENRL	Pain/ body aches	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
			Pyrexia/ fever	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
>55/ C459100 1 1066 10661327	3	GASTR	Diarrhoea/ diarrhea	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
			Vomiting/ vomiting	2	02NOV2020	1/1	1	Yes		NA	R (02NOV2020)	N/N
		GENRL	Chills/ chills	2	02NOV2020	1/1	1	Yes		NA	R (02NOV2020)	N/N
			Fatigue/ fatigue	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pain/ body aches	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
>55/ C459100 1 1066 10661328	3	GENRL	Chills/ chills	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
>55/ C459100 1 1066 10661334	3	GENRL	Fatigue/ fatigue	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
			Pyrexia/ fever	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
		NERV	Headache/ headache	2	05NOV2020	2/3	1	Yes		NA	R (07NOV2020)	N/N
		SKIN	Hyperhidrosis/ sweating	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
>55/ C459100 1 1066 10661350	3	CARD	Myocardial infarction/ myocardial infarction	1	03NOV2020	16/1	4	No	O	P/W	F (03NOV2020)	Y/N
>55/ C459100 1 1066 10661351	3	GENRL	Injection site pain/ pain at injection site	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
>55/ C459100 1 1066 10661353	3	GENRL	Chills/ chills	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Injection site pain/ pain at injection site	1	19OCT2020	1/3	1	Yes		NA	R (21OCT2020)	N/N
>55/ C459100 1 1066 10661354	3	GENRL	Injection site pain/ pain at injection site	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
>55/ C459100 1 1066 10661376	3	GENRL	Pain/ body aches	2	14NOV2020	2/C	1	Yes		NA	N	N/N
			Pyrexia/ fever	2	14NOV2020	2/C	1	Yes		NA	N	N/N
		NERV	Headache/ headache	2	14NOV2020	2/C	1	Yes		NA	N	N/N
>55/ C459100 1 1066 10661383	3	GENRL	Injection site pain/ pain at injection site	1	24OCT2020	2/4	1	Yes		NA	R (27OCT2020)	N/N
>55/ C459100 1 1083 10831283	3	GENRL	Chills/ Chills	2	13NOV2020	3/1	1	Yes		NA	R (13NOV2020)	N/N
			Pyrexia/ Fever 100.9 Fahrenheit	2	13NOV2020	3/1	1	Yes		NA	R (13NOV2020)	N/N
>55/ C459100 1 1084 10841490	3	MUSC	Back pain/ Back Pain	1	05NOV2020	21/1	2	No	O	NA/TC	R (05NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Va x Rel ^c	Caus e of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1084 10841504	3	INJ&P	Arthropod bite/ bug bite on left leg	1	08NOV2020	21/C	2	No	O	NA/TC	RG	N/N
>55/ C459100 1 1084 10841528	3	INJ&P	Fall/ Fall	1	08NOV2020	17/1	1	No	O	NA	R (08NOV2020)	N/N
			Skin abrasion/ ABRASION to FOREHEAD	1	08NOV2020	17/1	1	No	O	NA	R (08NOV2020)	N/N
>55/ C459100 1 1087 10871537	3	REPRO	Benign prostatic hyperplasia/ Worsening of Benign Prostatic Hyperplasia	1	12OCT2020	1/1	1	No	O	NA/TCN	R (12OCT2020)	N/N
>55/ C459100 1 1087 10871538	3	INFEC	Eye infection bacterial/ UNSPECIFIED RIGHT EYE BACTERIAL INFECTION	1	12OCT2020	1/6	2	No	O	NA/TC	R (17OCT2020)	N/N
>55/ C459100 1 1087 10871564	3	MUSC	Myalgia/ Generalized muscle aches	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100 1 1090 10901511	3	GENRL	Injection site pain/ Injection site pain-left arm	2	11NOV2020	1/C	1	Yes		NA	RG	N/N
			Pain/ Body aches	2	11NOV2020	1/C	2	Yes		NA	RG	N/N
		NERV	Headache/ Headache	2	12NOV2020	2/C	2	Yes		NA/TC	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1090 10901521	3	GENRL	Fatigue/ fatigue	2	12NOV2020	2/2	3	Yes		NA	R (13NOV2020)	N/N
>55/ C459100 1 1090 10901533	3	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/2	1	Yes		NA/TC	R (24OCT2020)	N/N
		NERV	Headache/ Headache	1	23OCT2020	2/2	1	Yes		NA/TC	R (24OCT2020)	N/N
>55/ C459100 1 1090 10901534	3	GENRL	Injection site pain/ Injection site pain-left arm	1	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
>55/ C459100 1 1090 10901541	3	GENRL	Pyrexia/ Fever	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
>55/ C459100 1 1090 10901549	3	GENRL	Injection site pain/ Injection site pain-left arm	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
>55/ C459100 1 1090 10901553	3	EAR	Vertigo positional/ positional vertigo, intermittent	1	27OCT2020	2/C	2	Yes		NA	N	N/N
>55/ C459100 1 1091 10911364	3	GENRL	Injection site pain/ Injection site pain	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1091 10911365	3	GENRL	Pyrexia/ Fever	2	06NOV2020	2/C	1	Yes		NA	N	N/N
		MUSC	Myalgia/ Myalgias	2	06NOV2020	2/C	1	Yes		NA	N	N/N
		NERV	Headache/ Headache	2	05NOV2020	1/4	1	Yes		NA/TC	R (08NOV2020)	N/N
		MUSC	Joint swelling/ joint swelling bilateral knees	2	06NOV2020	2/C	2	Yes		NA/TC	RG	N/N
		EYE	Eye inflammation/ worsen of inflammation bilateral eyes recurrent	2	10NOV2020	6/C	1	No	O	NA	N	N/N
>55/ C459100 1 1091 10911374	3	GENRL	Pain/ body aches	2	10NOV2020	2/C	1	Yes		NA	N	N/N
			Pyrexia/ fever	2	10NOV2020	2/C	1	Yes		NA	N	N/N
		NERV	Headache/ headache	2	10NOV2020	2/C	1	Yes		NA	N	N/N
>55/ C459100 1 1092 10921221	3	GENRL	Chills/ Chills	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
			Injection site pain/ Injection site tenderness	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
			Pyrexia/ Fever	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1092 10921230	3	NERV	Headache/ Headache	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
		GENRL	Pyrexia/ Fever of 99.2	1	14OCT2020	3/2	1	Yes		NA/TC	R (15OCT2020)	N/N
>55/ C459100 1 1092 10921259	3	GENRL	Pyrexia/ Fever	2	03NOV2020	2/C	1	Yes		NA	N	N/N
		GENRL	Pain/ body aches	2	12NOV2020	2/C	1	Yes		NA	N	N/N
>55/ C459100 1 1092 10921264	3	NERV	Pyrexia/ fever	2	12NOV2020	2/C	1	Yes		NA	N	N/N
		NERV	Paraesthesia/ paresthesia of left limb	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
>55/ C459100 1 1092 10921266	3	GENRL	Injection site pain/ Injection site tenderness	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
		NERV	Paraesthesia/ paresthesia of left limb	2	11NOV2020	1/C	1	Yes		NA	N	N/Y
>55/ C459100 1 1092 10921266	3	INFEC	Cellulitis/ Cellulitis (of the left calf)	1	28OCT2020	8/C	2	No	O	NA/TC	N	N/N
>55/ C459100	3	GENRL	Injection site pain/ injection site pain	1	28OCT2020	1/4	2	Yes		NA	R (31OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1092 10921275 >55/ C459100	3	INFEC	Sinusitis bacterial/ BACTERIAL SINUSITIS	1	09NOV2020	20/C	1	No	O	NA/TC	RG	N/N
1 1093 10931190 >55/ C459100	3	GENRL	Injection site pain/ pain at injection site left arm	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
1 1095 10951276 >55/ C459100	3	GENRL	Chills/ Chills	1	16OCT2020	3/3	1	Yes		NA	R (18OCT2020)	N/N
1 1098 10981257 >55/ C459100	3	GENRL	Injection site pain/ pain at site injection	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N
1 1110 11101351		INV	Body temperature increased/ elevated temperature	2	07NOV2020	2/2	1	Yes		NA/TC	R (08NOV2020)	N/N
		MUSC	Myalgia/ muscle pain	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N
		NERV	Headache/ headache	2	07NOV2020	2/2	1	Yes		NA/TC	R (08NOV2020)	N/N
>55/ C459100 1 1110 11101359	3	GENRL	Injection site pain/ pain at injection site	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1110 11101366	3	INFEC	Tooth abscess/ Tooth Abscess	1	20OCT2020	5/3	2	No	O	NA/TC/TCN	R (22OCT2020)	N/N
		GENRL	Injection site pain/ Pain at site injection	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		GENRL	Injection site pain/ Pain at site Injection	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
		GASTR	Nausea/ Nausea	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
		GENRL	Chills/ Chills	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
			Fatigue/ Fatigue	2	12NOV2020	2/C	2	Yes		NA	N	N/N
		MUSC	Myalgia/ Muscle pain	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
>55/ C459100 1 1110 11101376	3	NERV	Headache/ Headache	2	12NOV2020	2/1	2	Yes		NA	R (12NOV2020)	N/N
		MUSC	Muscle spasms/ Bilateral Lower Extremity Cramps	1	28OCT2020	1/1	1	No	O	NA/TC/TCN	R (28OCT2020)	N/N
		NERV	Headache/ headache	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
>55/ C459100 1 1111 11111193	3	GASTR	Pancreatitis acute/ Acute Pancreatitis	1	19OCT2020	5/3	3	No	O	NA/TC	R (21OCT2020)	Y/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11112 11121295	3	GENRL	Injection site pain/ Pain at the injection site	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C459100 11112 11121306	3	MUSC	Myalgia/ Muscle Aches	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
		NERV	Headache/ Headache	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
>55/ C459100 11112 11121309	3	GENRL	Vaccination site pain/ Pain at the injection site, post vaccination	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 11112 11121312	3	GENRL	Injection site pain/ Injection site pain, post vaccination	1	15OCT2020	2/3	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 11112 11121337	3	GASTR	Diarrhoea/ Diarrhea	1	22OCT2020	2/4	3	Yes		NA/TC/W	R (25OCT2020)	N/N
			Nausea/ Nausea	1	22OCT2020	2/4	2	Yes		NA/TC	RG (25OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	22OCT2020	2/7	2	Yes		P	R (28OCT2020)	N/N
		MUSC	Myalgia/ Muscle Aches	1	22OCT2020	2/7	2	Yes		NA/TC	R (28OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1112 11121347		NERV	Headache/ Headache	1	22OCT2020	2/7	2	Yes		NA/TC	R (28OCT2020)	N/N
		GASTR	Vomiting/ Vomiting	1	25OCT2020	5/1	2	Yes		NA	R (25OCT2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	13NOV2020	2/1	1	Yes		NA/TC	R (13NOV2020)	N/N
		NERV	Headache/ Headache	2	13NOV2020	2/1	1	Yes		NA/TC	R (13NOV2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	14NOV2020	3/C	1	Yes		NA/TC	RG	N/N
		INFEC	Fungal skin infection/ FUNGUS, TOE, RIGHT GREAT	1	26OCT2020	15/C	1	No	O	NA	N	N/N
		SURG	Micrographic skin surgery/ Mohs surgery left arm	1	03NOV2020	13/1	2	No	O	NA	R (03NOV2020)	N/N
		GENRL	Oedema peripheral/ BOTH LOWER EXTREMITY EDEMA	2	10NOV2020	1/C	1	No	O	NA	N	N/N
>55/ C459100 1 1120 11201358	3	PSYCH	Depression/ worsening of depression	1	29OCT2020	2/C	2	Yes		P	N	N/N
>55/ C459100 1 1120 11201408	3											

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11122 11221057	3	GENRL	Non-cardiac chest pain/ non cardiac chest pain	1	21OCT2020	6/1	1	Yes		NA	R (21OCT2020)	N/N
>55/ C459100 11122 11221060	3	GASTR	Diarrhoea/ diarrhea	1	22OCT2020	1/2	2	Yes		NA	R (23OCT2020)	N/N
		GENRL	Pain/ body aches	1	22OCT2020	1/2	2	Yes		NA	R (23OCT2020)	N/N
		NERV	Headache/ headache	1	22OCT2020	1/2	2	Yes		NA	R (23OCT2020)	N/N
		GENRL	Fatigue/ mild fatigue	2	11NOV2020	2/C	1	Yes		NA/TC	RG	N/N
			Pain/ mild body aches	2	11NOV2020	2/C	1	Yes		NA/TC	RG	N/N
>55/ C459100 11123 11231368	3	GENRL	Injection site pain/ Pain at injection site	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
			Injection site swelling/ Swelling at injection site	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 11129 11291222	3	GENRL	Chills/ chills	2	03NOV2020	1/C	2	Yes		NA/TC	RG	N/N
		MUSC	Arthralgia/ joint pain-generalized	2	03NOV2020	1/C	2	Yes		NA/TC	N	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Myalgia/ muscle pain	2	03NOV2020	1/C	2	Yes		NA/TC	N	N/N
>55/ C459100 11129 11291232	3	INFE	Urinary tract infection/ urinary tract infection	1	01NOV2020	19/C	1	No	O	NA/TC	RG	N/N
>55/ C459100 11131 11311237	3	GENRL	Fatigue/ fatigue	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
			Injection site pain/ Injection site pain	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		NERV	Headache/ headache	1	26OCT2020	15/C	1	No	O	NA/TC	RG	N/N
		RESP	Sinus congestion/ sinus congestion	1	26OCT2020	15/C	1	No	O	NA	N	N/N
>55/ C459100 11131 11311238	3	GASTR	Nausea/ nausea	1	13OCT2020	1/32	1	Yes		NA	R (13NOV2020)	N/Y
		VASC	Hypertension/ worsening of hypertension	1	14OCT2020	2/17	1	No	O	NA/TC	R (30OCT2020)	N/N
>55/ C459100 11131 11311245	3	GENRL	Injection site bruising/ bruising at injection site	1	15OCT2020	1/C	1	No	O	NA	N	N/N
		INFE	Urinary tract infection/ urinary tract infection	1	03NOV2020	20/8	2	No	O	NA/TC	R (10NOV2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11131 11311249	3	GENRL	Pyrexia/ low grade temperature elevation	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
>55/ C459100 11134 11341412	3	GASTR	Diarrhoea/ Loose Stools	1	22OCT2020	10/10	1	Yes		NA	R (31OCT2020)	N/N
>55/ C459100 11136 11361075	3	GENRL	Injection site pain/ injection site tenderness	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
>55/ C459100 11136 11361079	3	GASTR	Nausea/ nausea	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
>55/ C459100 11136 11361080	3	MUSC	Neck pain/ neck pain	1	28OCT2020	7/C	1	No	O	NA	RG	N/N
		NERV	Headache/ headaches	1	28OCT2020	7/C	1	No	O	NA/TC	RG	N/N
		GENRL	Axillary pain/ right arm pit pain	1	06NOV2020	16/2	1	No	O	NA	R (07NOV2020)	N/N
>55/ C459100 11136 11361096	3	GENRL	Chills/ chills	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
			Pain/ body aches	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11140 11401280	3	NERV	Dizziness/ Light headed	1	16OCT2020	4/1	2	No	O	NA	R (16OCT2020)	N/N
>55/ C459100 11140 11401283	3	GASTR	Diarrhoea/ Loose Stool	1	18OCT2020	5/1	1	No	O	NA	R (18OCT2020)	N/N
>55/ C459100 11140 11401288	3	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
		GENRL	Chills/ Chills	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
			Pyrexia/ Fever	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
>55/ C459100 11140 11401305	3	GENRL	Injection site pain/ Pain at injection site	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/Y
>55/ C459100 11141 11411268	3	UNC	INJECTION SITE PAIN@@/ injection site pain	1	27OCT2020	2/3	1			NA	R (29OCT2020)	N/N
		UNC	FOLLICULITIS RIGHT AXILLARY@@/ folliculitis right axillary	1	06NOV2020	12/C	1			NA	RG	N/N
>55/ C459100	3	GENRL	Injection site bruising/ Bruising at injection site	1	27OCT2020	1/C	1	Yes		NA	RG	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1142 11421304 >55/ C459100 1 1152 11521514	3	GENRL	Chills/ Chills	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
			Injection site pain/ Injection Site Soreness	2	04NOV2020	1/6	1	Yes		NA	R (09NOV2020)	N/N
		GENRL	Fatigue/ Fatigue	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
>55/ C459100 1 1152 11521516	3	CARD	Atrial fibrillation/ worsening of atrial fibrillation	1	17OCT2020	5/12	2	No	O	NA/TC	R (28OCT2020)	N/N
>55/ C459100 1 1152 11521524	3	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/4	1	Yes		NA	R (08NOV2020)	N/N
		MUSC	Myalgia/ Muscle Aches	2	05NOV2020	1/4	1	Yes		NA	R (08NOV2020)	N/N
		GASTR	Nausea/ Nausea	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
		GENRL	Chills/ Chills	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
		NERV	Headache/ Headache	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
		GASTR	Diarrhoea/ Diarrhea	2	08NOV2020	4/1	2	Yes		NA/TC	R (08NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11152 11521528	3	GASTR	Diarrhoea/ Diarrhea	1	15OCT2020	1/2	2	Yes		NA	R (16OCT2020)	N/N
		NERV	Headache/ Headache	1	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	1	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
		MUSC	Myalgia/ Myalgia	2	05NOV2020	1/3	1	Yes		NA/TC	R (07NOV2020)	N/N
		NERV	Headache/ Headache	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/N
		GENRL	Pyrexia/ Fever	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
>55/ C459100 11152 11521540	3	GENRL	Chills/ Chills	2	04NOV2020	1/3	1	Yes		NA/TC	R (06NOV2020)	N/N
			Fatigue/ Fatigue	2	04NOV2020	1/3	1	Yes		NA/TC	R (06NOV2020)	N/N
		MUSC	Pain in extremity/ Arm Soreness	2	04NOV2020	1/4	1	Yes		NA/TC	R (07NOV2020)	N/N
		NERV	Headache/ Headache	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
		MUSC	Myalgia/ Myalgia	2	06NOV2020	3/1	1	Yes		NA	R (06NOV2020)	N/N
>55/ C459100	3	INFEC	Ear infection/ left ear infection	1	24OCT2020	4/12	1	No	O	NA	R (04NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1152 11521553		INFECTION	Gingival abscess/ gum abscess	1	28OCT2020	8/C	1	No	O	NA/TC	N	N/N
>55/ C459100 1 1152 11521562	3	GENRL	Malaise/ malaise	1	22OCT2020	1/1	2	Yes		NA/TC	R (22OCT2020)	N/N
			Pain/ body aches	1	22OCT2020	1/1	2	Yes		NA/TC	R (22OCT2020)	N/N
		NERV	Headache/ intermittent headache	1	22OCT2020	1/5	2	Yes		NA/TC	R (26OCT2020)	N/N
		MUSC	Arthralgia/ sore left shoulder	1	23OCT2020	2/4	2	Yes		NA	R (26OCT2020)	N/N
		NERV	Dizziness/ dizziness	2	10NOV2020	1/1	1	No	O	NA	R (10NOV2020)	N/Y
>55/ C459100 1 1152 11521563	3	MUSC	Pain in extremity/ right arm soreness	1	22OCT2020	1/5	2	Yes		NA/TC	R (26OCT2020)	N/N
		NERV	Headache/ intermittent headache	1	23OCT2020	2/4	1	Yes		NA	R (26OCT2020)	N/N
>55/ C459100 1 1156 11561279	3	GASTR	Diarrhoea/ DIARRHEA	1	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	1	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11157 11571150	3	MUSC	Myalgia/ Myalgia (Whole Body)	2	03NOV2020	2/4	1	Yes		NA	R (06NOV2020)	N/N
		NERV	Headache/ Headache	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
>55/ C459100 11157 11571178	3	GASTR	Diarrhoea/ Diarrhea	1	26OCT2020	1/1	1	Yes		NA	R (26OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
>55/ C459100 11168 11681240	3	GENRL	Injection site erythema/ redness at the injection site	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
			Injection site pruritus/ itching at the injection site	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
			Injection site swelling/ swelling at the injection site	1	27OCT2020	2/9	1	Yes		NA	R (04NOV2020)	N/N
>55/ C459100 11170 11701448	3	GENRL	Chills/ Chills	1	28OCT2020	3/2	1	Yes		NA	R (29OCT2020)	N/N
			Fatigue/ Fatigue	1	28OCT2020	3/3	1	Yes		NA	R (30OCT2020)	N/N
>55/ C459100	3	INJ&P	Fall/ Fall	1	25OCT2020	12/1	2	No	O	NA/TCN	R (25OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1177 11771508			Wrist fracture/ Fractured Right Wrist	1	25OCT2020	12/C	2	No	O	NA/TCN	RG	N/N
>55/ C459100 1 1177 11771527	3	GENRL	Injection site pain/ INJECTION SITE MUSCLE PAIN	1	19OCT2020	1/2	2	Yes		NA/TC	R (20OCT2020)	N/N
			Injection site swelling/ SWELLING AT INJECTION SITE	1	19OCT2020	1/4	1	Yes		NA/TC	R (22OCT2020)	N/N
		GASTR	Abdominal pain/ ABDOMINAL PAIN	1	31OCT2020	13/2	1	No	O	NA	R (01NOV2020)	N/N
			Nausea/ NAUSEA	1	31OCT2020	13/2	1	No	O	NA	R (01NOV2020)	N/N
>55/ C459100 1 1178 11781297	3	GENRL	Injection site pain/ Injection site tenderness, right arm	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/Y
		RESP	Epistaxis/ epistaxis	1	20OCT2020	7/1	1	No	O	NA	R (20OCT2020)	N/N
>55/ C459100 1 1178 11781303	3	GENRL	Chills/ chills	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
			Fatigue/ fatigue	1	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N
>55/ C459100	3	GENRL	Injection site pain/ Soreness at injection site	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1178 11781306 >55/ C459100 1 1194 11941060	3	GASTR	Aphthous ulcer/ aphthous ulcer	2	09NOV2020	1/3	1	No	O	NA	R (11NOV2020)	N/N
>55/ C459100 1 1194 11941076	3	RESP	Oropharyngeal pain/ Sore throat	1	27OCT2020	8/1	1	No	CND	NA	R (27OCT2020)	N/N
>55/ C459100 1 1195 11951011	3	MUSC	Myalgia/ muscular pain (sore muscles)	1	27OCT2020	13/1	1	No	O	NA	R (27OCT2020)	N/N
>55/ C459100 1 1195 11951016	3	GASTR	Diarrhoea/ Diarrhea	1	22OCT2020	8/1	1	No	O	NA	R (22OCT2020)	N/N
>55/ C459100 1 1195 11951044	3	GASTR	Diarrhoea/ Diarrhoe (fatty food)	1	24OCT2020	9/1	1	No	O	NA	R (24OCT2020)	N/N
>55/ C459100 1 1197 11971006	3	MUSC	Osteoarthritis/ worsening of activated arthrosis	1	17OCT2020	3/3	2	No	CD	NA/TC	R (19OCT2020)	N/N
>55/ C459100 1 1197 11971016	3	EYE	Conjunctival haemorrhage/ Hyposphagma left	1	17OCT2020	2/4	1	No	CD	NA	R (20OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11197 11971047	3	VASC	Hypertension/ worsening hypertension	1	20OCT2020	4/11	1	No	O	NA	R (30OCT2020)	N/N
>55/ C459100 11197 11971051	3	EYE	Cataract/ cataract left eye	1	05NOV2020	20/C	1	No	O	NA	N	N/N
>55/ C459100 11197 11971084	3	GASTR	Haemorrhoids/ hemorrhoids	1	27OCT2020	9/C	1	No	O	NA	N	N/N
		NEOPL	Colon adenoma/ Colon adenoma	1	27OCT2020	9/1	1	No	O	NA/TCN	R (27OCT2020)	N/N
>55/ C459100 11203 12031003	3	MUSC	Joint swelling/ swollen thumb joint left	1	05NOV2020	21/C	1	No	O	NA	N	N/N
>55/ C459100 11203 12031016	3	NERV	Headache/ headache	1	30OCT2020	12/1	2	No	O	NA/TC	R (30OCT2020)	N/N
>55/ C459100 11203 12031017	3	MUSC	Myalgia/ sore muscles (lower back and upper legs)	1	07NOV2020	20/C	1	No	O	NA	RG	N/N
		GENRL	Fatigue/ fatigue	1	09NOV2020	22/C	1	No	O	NA	RG	N/N
>55/ C459100	3	MUSC	Pain in extremity/ pain left foot	1	09NOV2020	21/1	2	No	O	NA/TC	R (09NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value of AE ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1203 12031027 >55/ C459100 1 1204 12041213	3	GENRL	Vaccination site pain/ left arm soreness (vac 1 site)	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
>55/ C459100 1 1204 12041219	3	GENRL	Pyrexia/ mild fever, body temperature 99.1	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		VASC	Flushing/ Feeling flushed, generalized	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
			Injection site pain/ Muscle tenderness at injection site	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
		NERV	Headache/ Headache	1	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
		GENRL	Pyrexia/ Low grade fever, 100.5	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
>55/ C459100 1 1204 12041229	3	GENRL	Vaccination site pain/ left arm soreness (vac#1 injection site)	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
>55/ C459100 1 1204 12041254	3	GENRL	Vaccination site pain/ left arm soreness (vac#1 injection site)	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Muscle Aches	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
		NERV	Headache/ Persistent Headache	2	06NOV2020	1/2	2	Yes		NA/TC	R (07NOV2020)	N/N
		GENRL	Injection site pain/ muscle tenderness at injection site	2	08NOV2020	3/C	1	Yes		NA	RG	N/N
		GENRL	Injection site erythema/ erythema at injection site	2	09NOV2020	4/C	1	Yes		NA	RG	N/N
			Injection site pruritus/ pruritus at injection site	2	09NOV2020	4/C	1	Yes		NA	RG	N/N
			Injection site swelling/ swelling at injection site	2	09NOV2020	4/C	1	Yes		NA	RG	N/N
>55/ C459100 1 1204 12041266	3	GENRL	Fatigue/ fatigue	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
			Pyrexia/ felt feverish	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
>55/ C459100 1 1204 12041291	3	GENRL	Pyrexia/ fever	2	14NOV2020	2/C	1	Yes		NA	RG	N/N
>55/ C459100 1 1220 12201014	3	GENRL	Injection site pain/ soreness in arm at injection site	1	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
			Pain/ body aches	1	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1221 12211001	3	GENRL	Chills/ Chills	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
			Injection site pain/ Injection site tenderness	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
>55/ C459100 1 1221 12211009	3	IMMUN	Seasonal allergy/ Seasonal Allergies	1	16OCT2020	1/3	1	No	O	NA	R (18OCT2020)	N/N
>55/ C459100 1 1221 12211021	3	METAB	Decreased appetite/ Loss of appetite	1	30OCT2020	1/2	1	Yes		NA/TCN	R (31OCT2020)	N/N
		NERV	Headache/ Headache	1	30OCT2020	1/3	1	Yes		NA/TCN	R (01NOV2020)	N/N
		GENRL	Fatigue/ Fatigue	1	02NOV2020	4/5	2	Yes		NA	R (06NOV2020)	N/N
>55/ C459100 1 1221 12211028	3	GENRL	Injection site pain/ Injection site pain, Left arm	1	05NOV2020	1/C	2	Yes		NA/TC	RG	N/N
		SKIN	Pruritus/ Localized pruritis, left scapula, distal end	1	05NOV2020	1/C	1	Yes		NA	RG	N/N
>55/ C459100 1 1223 12231262	3	GENRL	Fatigue/ fatigue*		21OCT2020	1/2	2	Yes		NA	R (22OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1223 12231266	3	MUSC	Pain in extremity/ arm soreness	1	22OCT2020	2/3	2	Yes		NA/TC	R (24OCT2020)	N/N
		GENRL	Chills/ chills	1	23OCT2020	1/2	2	Yes		NA	R (24OCT2020)	N/N
>55/ C459100 1 1226 12262158	3	MUSC	Myalgia/ myalgia	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
			Pain in extremity/ left arm soreness	1	23OCT2020	1/2	2	Yes		NA/TC	R (24OCT2020)	N/N
		NERV	Headache/ headache	1	24OCT2020	2/1	2	Yes		NA	R (24OCT2020)	N/N
		GENRL	Injection site pain/ Pain at the injection site	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
>55/ C459100 1 1226 12262175	3	GENRL	Malaise/ Indisposition	2	04NOV2020	2/1	2	Yes		NA/TC	R (04NOV2020)	N/N
>55/ C459100 1 1226 12262176	3	INFEC	Parotitis/ (left) Parotitis	2	05NOV2020	3/C	1	No	O	NA	RG	N/N
>55/ C459100 1 1226 12262180	3	GENRL	Fatigue/ Fatigue	1	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		MUSC	Myalgia/ Muscle pain	1	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
				1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
		NERV	Headache/ Headache	1	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
>55/ C459100 1 1226 12262207	3	GENRL	Chills/ chills	1	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
		NERV	Headache/ headache	1	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
>55/ C459100 1 1226 12262222	3	GENRL	Injection site pain/ Pain at the injection site	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N
>55/ C459100 1 1226 12262235	3	MUSC	Arthralgia/ Joint pain	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N
			Myalgia/ muscle pain	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N
		NERV	Headache/ Headache	1	17OCT2020	2/1	2	Yes		NA/TC	R (17OCT2020)	N/N
>55/ C459100	3	BLOOD	Lymphadenopathy/ (Left) axillary lymph node enlargement	1	16OCT2020	1/10	2	Yes		NA	R (25OCT2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1226 12262238		GENRL	Injection site erythema/ Redness at injection site	1	16OCT2020	1/10	2	Yes		NA	R (25OCT2020)	N/N
			Injection site oedema/ Edema at injection site	1	16OCT2020	1/10	2	Yes		NA	R (25OCT2020)	N/N
			Injection site pain/ Pain at local injection	1	16OCT2020	1/10	2	Yes		NA	R (25OCT2020)	N/N
>55/ C459100 1 1226 12262240	3	INJ&P	Fall/ fall from own height	1	24OCT2020	9/1	1	No	O	NA	R (24OCT2020)	N/N
			Femur fracture/ Fracture of the right femur	1	24OCT2020	9/6	3	No	O	NA/TCN	R (29OCT2020)	Y/N
>55/ C459100 1 1226 12262248	3	GENRL	Injection site pain/ Pain at injection site	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 1226 12262254	3	GASTR	Diarrhoea/ Diarrhea	1	25OCT2020	10/2	2	Yes		NA	R (26OCT2020)	N/N
>55/ C459100 1 1226 12262257	3	MUSC	Myalgia/ Muscle pain	2	07NOV2020	2/1	1	Yes		NA	R (07NOV2020)	N/N
		NERV	Somnolence/ Somnolence	2	07NOV2020	2/1	1	Yes		NA	R (07NOV2020)	N/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)	
>55/ C459100 1 1226 12262305	3	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	1	Yes		NA	RS (18OCT2020)	N/N	
			Chills/ Chills	1	18OCT2020	2/1	1	Yes		NA	R (18OCT2020)	N/N	
			Pyrexia/ Fever 38.4 C	1	18OCT2020	2/1	1	Yes		NA/TC	R (18OCT2020)	N/N	
			Headache/ Headache	1	18OCT2020	2/1	1	Yes		NA	R (18OCT2020)	N/N	
>55/ C459100 1 1226 12262308	3	GENRL	Injection site pain/ Pain at injection site	1	17OCT2020	1/2	2	Yes		NA/TC	R (18OCT2020)	N/N	
			NERV	Hyperaesthesia/ Increased pain sensitivity in left hemcranial region	1	28OCT2020	12/14	2	No	O	NA/TC	R (10NOV2020)	N/N
				Fatigue/ fatigue	2	07NOV2020	2/2	2	Yes		NA/TC	R (08NOV2020)	N/N
				Pyrexia/ fever (38,2 C)	2	07NOV2020	2/2	2	Yes		NA/TC	R (08NOV2020)	N/N
				MUSC	Myalgia/ muscle pain	2	07NOV2020	2/2	2	Yes		NA/TC	R (08NOV2020)
>55/ C459100 1 1226 12262325	3	GENRL	Injection site erythema/ Redness at injection site	1	20OCT2020	2/3	2	Yes		NA	R (22OCT2020)	N/N	
			Injection site pain/ Pain at injection site	1	20OCT2020	2/3	2	Yes		NA	R (22OCT2020)	N/N	

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 1 1226 12262332	3	GENRL	Injection site pain/ Pain at injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/Y
		NERV	Headache/ Headache	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
		RESP	Cough/ Dry cough	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
>55/ C459100 1 1226 12262336	3	GENRL	Fatigue/ fatigue	1	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
			Injection site pain/ pain at injection site	1	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
>55/ C459100 1 1226 12262344	3	GASTR	Diarrhoea/ Diarrhea	2	08NOV2020	2/C	1	Yes		NA	RG	N/N
>55/ C459100 1 1226 12262345	3	GENRL	Chills/ chills	1	21OCT2020	3/1	1	Yes		NA	R (21OCT2020)	N/N
>55/ C459100 1 1226 12262349	3	GENRL	Asthenia/ asthenia	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
>55/ C459100 1 1226 12262355	3	MUSC	Back pain/ Backache	1	26OCT2020	7/1	1	Yes		NA	R (26OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C459100 11229 12291183	3	MUSC	Arthralgia/ Pain right hip	1	19OCT2020	8/C	1	No	O	NA/TC/TCN	N	N/N
>55/ C459100 11235 12351177	3	MUSC	Musculoskeletal pain/ Myalgia and arthralgia	1	27OCT2020	14/2	1	No	O	NA	R (28OCT2020)	N/N
>55/ C459100 11235 12351179	3	GENRL	Fatigue/ Fatigue	1	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N
		MUSC	Pain in extremity/ Arm soreness	1	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 11235 12351182	3	NERV	Headache/ Cephalgia	1	21OCT2020	2/3	1	Yes		NA/TC	R (23OCT2020)	N/N
>55/ C459100 11235 12351201	3	GENRL	Chills/ Chills	2	12NOV2020	2/C	1	Yes		NA	N	N/N
		INV	Body temperature increased/ Elevated temperature	2	12NOV2020	2/C	1	Yes		NA	N	N/N
		MUSC	Myalgia/ Myalgia of bilateral shoulders and left arm	2	12NOV2020	2/C	1	Yes		NA	N	N/N
>55/ C459100	3	INV	Body temperature increased/ Elevated temperature	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1235 12351202		NERV	Headache/ Cephalgia	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
>55/ C459100 1 1235 12351213	3	GENRL	Fatigue/ Fatigue	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
		GENRL	Chills/ Chills	2	11NOV2020	2/1	1	Yes		NA	R (11NOV2020)	N/N
>55/ C459100 1 1241 12412191	3	PSYCH	Disorientation/ Disorientation to clarify	2	09NOV2020	4/4	3	No	O	NA/TC	R (12NOV2020)	Y/N
>55/ C459100 1 1241 12412205	3	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 1241 12412219	3	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
>55/ C459100 1 1241 12412241	3	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/1	1	Yes		NA	R (16OCT2020)	N/N
>55/ C459100	3	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA/TCN	R (17OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1241 12412242 >55/ C459100	3	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	1	Yes		NA	R (22OCT2020)	N/N
1 1241 12412356 >55/ C459100	3	GASTR	Diarrhoea/ Diarrhea	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
1 1241 12412483 >55/ C459100	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
1 1241 12412487 >55/ C459100	3	GENRL	Chills/ Chills	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
1 1241 12412488 Fatigue/ Fatigue				1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
>55/ C459100 1 1241 12412497	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
>55/ C459100 1 1241 12412499	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ Fever	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
>55/ C459100 1 1241 12412533	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
>55/ C459100 1 1241 12412542	3	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
>55/ C459100 1 1241 12412555	3	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
>55/ C459100 1 1251 12511243	3	GASTR	Abdominal pain/ Abdominal Pain	1	30OCT2020	17/1	3	No	O	NA/TC	R (30OCT2020)	N/N
			Nausea/ nausea	1	30OCT2020	17/1	3	No	O	NA/TC	R (30OCT2020)	N/N
			Vomiting/ vomiting	1	30OCT2020	17/1	3	No	O	NA/TC	R (30OCT2020)	N/N
>55/ C459100 1 1251 12511244	3	RESP	Oropharyngeal pain/ sore throat	1	21OCT2020	7/1	1	Yes		NA	R (21OCT2020)	N/N
		RESP	Epistaxis/ worsening of epistaxis right nostril	1	27OCT2020	13/1	1	Yes		NA	R (27OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Value ^c of AE	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		RESP	Epistaxis/ worsening of epistaxis right nostril	1	02NOV2020	19/1	1	Yes		NA	R (02NOV2020)	N/N
>55/ C459100 1 1254 12541192	3	GENRL	Injection site pain/ injection site soreness	1	18OCT2020	2/20	1	Yes		NA	R (06NOV2020)	N/N
		GASTR	Diarrhoea/ diarrhea	2	08NOV2020	2/2	1	Yes		NA	R (09NOV2020)	N/N
		NERV	Headache/ Headaches	2	08NOV2020	2/2	2	Yes		NA/TC	R (09NOV2020)	N/N
>55/ C459100 1 1254 12541200	3	GENRL	Pyrexia/ Fever at 100.3F	1	22OCT2020	2/1	1	Yes		NA/TC	R (22OCT2020)	N/N
>55/ C459100 1 1254 12541203	3	GENRL	Injection site erythema/ redness at injection site	1	24OCT2020	1/3	1	Yes		NA	R (26OCT2020)	N/N
			Injection site pain/ soreness at injection site	1	24OCT2020	1/2	1	Yes		NA	R (25OCT2020)	N/N
		NERV	Headache/ headache	1	24OCT2020	1/2	1	Yes		NA	R (25OCT2020)	N/N
>55/ C459100 1 1254 12541207	3	GENRL	Injection site pain/ injection site soreness	1	24OCT2020	1/2	1	Yes		NA	R (25OCT2020)	N/N
>55/ C459100	3	GENRL	Fatigue/ Fatigue	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N

16.2.7.4.4 Listing of Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1 1264 12641217			Pyrexia/ Fever	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
>55/ C459100 1 1264 12641223	3	UNC	HEADACHE@@/ Headache	1	23OCT2020	1/1	1	Yes		NA	R (23OCT2020)	N/N
			HEAT AT INJECTION SITE@@/ Heat at injection site	1	23OCT2020	1/1	1	Yes		NA	R (23OCT2020)	N/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

Note: Preferred terms with @@ denote uncoded terms.

Note: * = Prevaccination AE, ^ = Phase 2/3 38000 subject, † = HIV-positive subject.

Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.

a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:43)

(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_1002_all_p3

16.2.7.4.6 Listing of Adverse Events – Subjects Enrolled in Multiple Sites

Age Group (Years)/ Subject	System Organ Phase	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C4591001 1133 11331382	3 [^]	GENRL	Fatigue/ FATIGUE	2	26SEP2020	2/C	1	Yes	NA/TCN	N	N/N
			Injection site pain/ SORNESS AT INJECTION SITE	2	26SEP2020	2/C	1	Yes	NA/TC	N	N/N
			Pain/ BODYACHE	2	26SEP2020	2/C	2	Yes	NA/TC	N	N/N
			Pyrexia/ FEVER	2	26SEP2020	2/2	2	Yes	NA/TC	R (27SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	30SEP2020	6/C	2	Yes	NA/TC/TCN	N	N/N	

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

Note: * = Pre vaccination AE, [^] = Phase 2/3 38000 subject, † = HIV-positive subject.

a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (10:07)

(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_1002_menrol_p3

16.2.7.5.1 Listing of Serious Adverse Events – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)/ Subject	System Organ Class	Preferred	Investigator	Dose No.	Onset Date	Rel	Toxicity Grade	Vax Rel ^c	Cause of AE	Action:	Investigational Outcome (End Date)	SAE/ Imm (Yes/No)
				Term/ AE Text				Day ^{a/} (Days) ^b				Vaccine Dose/ Subject		
No subject meets the reporting criteria.														
Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions. Note: MedDRA (v23.0) coding dictionary applied. a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day. b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator. PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 29AUG2020 (09:41) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_1002_sae_p1														

16.2.7.5.1.1 Listing of Serious Adverse Events Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Vaccine Group (Years)	Vaccine Group Administered)/ Subject	System Organ Class	Preferred	Investigator	Dose No.	Onset Date	Rel Day ^{a/} (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
				Term/ AE Text										
No subject meets the reporting criteria.														
Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions. Note: MedDRA (v23.0) coding dictionary applied.														
a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.														
b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.														
c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.														
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 18SEP2020 (18:58) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adae_1002_sae_100_p1														

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel	Toxicity Grade	Vax Rel ^c	Cause of AE	Action:		Outcome (End Date)	SAE/ Imm (Yes/No)
					Day ^a / Dur (Days) ^b				Investigational Vaccine Dose/ Subject			
18-55/ C4591001 1079 10791004	NEOPL	Adenocarcinoma gastric/ INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	1	20AUG2020	23/C	3	No	O: n/a	P/W	N	Y/N	

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.0) coding dictionary applied.

- a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.
- b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.
- c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:08) Source Data: adae Table Generation: 10SEP2020 (21:41)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adae_1002_sae_p2

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C4591001 1005 10051054	3^	GENRL	Non-cardiac chest pain/ INTERMITTENT NON CARDIAC CHEST PAIN	2	09SEP2020	6/9	2	No	O	NA	R (17SEP2020)	Y/N
16-55/ C4591001 1007 10071276	3^	NEOPL	Chronic myeloid leukaemia/ chronic myelogenous leukemia	2	24SEP2020	8/C	4	No	O	NA/TC	N	Y/N
16-55/ C4591001 1013 10131084	3^	GENRL	Vascular stent occlusion/ OBSTRUCTED RENAL STENT (ARTERY)	2	01SEP2020	7/C	2	No	O	NA	RG	Y/N
16-55/ C4591001 1015 10151047	3^	GENRL	Shoulder injury related to vaccine administration/ SIRVA - shoulder injury related to vaccine administration	2	09SEP2020	1/C	3	Yes		NA	RG	Y/N
16-55/ C4591001 1016 10161277	3^	CARD	Atrial fibrillation/ atrial fibrillation	2	09OCT2020	8/4	2	No	O	NA/TC	R (12OCT2020)	Y/N
16-55/ C4591001 1016 10161289	3^	INJ&P	Facial bones fracture/ facial fractures	2	31OCT2020	25/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1018 10181159	3^	UNC	LOWER BACK PAIN AND BILATERAL LOWER EXTREMITY PAIN WITH RADICULAR PARESTHESIA@@/ Lower back pain and bilateral lower extremity	2	20OCT2020	47/C	2	Yes		NA/TC	RG	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C4591001 1019 10191254	3^	INFEC	pain with radicular paresthesia Urinary tract infection/ Urinary Tract Infection	1	15OCT2020	11/10	3	No	O	NA	R (24OCT2020)	Y/N
16-55/ C4591001 1028 10281059	3^	NEOPL	Invasive ductal breast carcinoma/ invasive ductal carcinoma stage 1B, left breast	2	30SEP2020	15/C	2	No	O	NA	N	Y/N
16-55/ C4591001 1028 10281060	3^	INJ&P	Upper limb fracture/ Closed fracture of right elbow	2	28OCT2020	42/2	2	No	O	NA/TC/TCN	R (29OCT2020)	Y/N
16-55/ C4591001 1055 10551176	3^	CARD	Arteriospasm coronary/ Coronary vasospasm	2	25SEP2020	3/2	3	No	O	NA	R (26SEP2020)	Y/N
16-55/ C4591001 1057 10571137	3^	NEOPL	Uterine leiomyoma/ WORSENING OF UTERINE FIBROIDS	1	14SEP2020	14/6	2	No	O	NA/TCN	R (19SEP2020)	Y/N
16-55/ C4591001 1079 10791004	2^	NEOPL	Adenocarcinoma gastric/ INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	1	20AUG2020	23/C	3	No	O	P/W	N	Y/N
16-55/ C4591001	3^	INFEC	Appendicitis/ Appendicitis	1	21AUG2020	9/3	3	No	O	NA/TC/TCN	R (23AUG2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1081 10811036												
16-55/ C4591001 1081 10811046	3^	METAB	Hyperglycaemia/ Hyperglycemic episode	2	17SEP2020	9/2	3	No	O	NA	R (18SEP2020)	Y/N
16-55/ C4591001 1081 10811135	3^	CARD	Myocardial infarction/ Myocardial Infarction	2	21OCT2020	30/C	4	No	O	NA/TC/TCN	RG	Y/N
		METAB	Type 2 diabetes mellitus/ New Onset Type II Diabetes Mellitus	2	21OCT2020	30/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1081 10811194	3^	GENRL	Death/ Death	2	01NOV2020	34/1	4	No	O	NA/W	F (01NOV2020)	Y/N
16-55/ C4591001 1083 10831029	3^	CARD	Atrial fibrillation/ Paroxysmal Atrial fibrillation with rapid ventricular response	1	23AUG2020	20/17	3	No	O	P/TC/TCN	R (08SEP2020)	Y/N
16-55/ C4591001 1083 10831060	3^	GASTR	Diverticular perforation/ Ruptured diverticulum	1	14AUG2020	9/11	4	No	O	P/TC/TCN	R (24AUG2020)	Y/N
16-55/ C4591001 1083 10831194	3^	CARD	Atrial fibrillation/ New Onset Atrial Fibrillation with rapid ventricular response	2	26OCT2020	34/C	2	No	O	NA/TC	RG	Y/N
16-55/ C4591001	3^	INFEC	Cellulitis/ Cellulitis in Left leg	1	08SEP2020	12/9	2	No	O	NA/TC/TCN	R (16SEP2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1084 10841317												
16-55/ C4591001 1088 10881220	3^	NEOPL	Meningioma/ right frontal meningioma	1	23SEP2020	6/C	2	No	O	NA	N	Y/N
16-55/ C4591001 1089 10891182	3^	INJ&P	Hip fracture/ Left Hip Closed Fracture	1	09SEP2020	16/17	3	No	O	NA/TC	R (25SEP2020)	Y/N
		PSYCH	Psychotic disorder/ Psychosis	1	27SEP2020	34/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1091 10911197	3^	INJ&P	Toxicity to various agents/ poisoning by cocaine	2	26SEP2020	10/2	4	No	O	NA/TC/TCN	R (27SEP2020)	Y/N
		RESP	Hypoxia/ hypoxia	2	26SEP2020	10/2	3	No	O	NA/TC/TCN	R (27SEP2020)	Y/N
			Pneumonia aspiration/ Aspiration Pneumonia	2	26SEP2020	10/11	3	No	O	NA/TC	R (06OCT2020)	Y/N
16-55/ C4591001 1091 10911300	3^	INFEC	Appendicitis/ Appendicitis	2	22OCT2020	17/2	4	No	O	NA/TCN	R (23OCT2020)	Y/N
16-55/ C4591001 1094 10941155	3^	INJ&P	Colon injury/ colon injury	1	16OCT2020	22/8	3	No	O	NA/TC/TCN	RS (23OCT2020)	Y/N
16-55/ C4591001	3^	CARD	Acute myocardial infarction/	1	05SEP2020	8/5	4	No	O	P/TC/TCN	R (09SEP2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1095 10951173			STEMI: ST elevation Myocardial Infarction									
16-55/ C4591001 1096 10961062	3^	METAB	Hypokalaemia/ HYPOKALEMIA	2	SEP2020	1/	3	No	O	NA/TC	R	Y/N
		NERV	Diplegia/ Bilateral Lower extremity paralysis	2	04OCT2020	26/2	3	No	O	NA	R (05OCT2020)	Y/N
16-55/ C4591001 1107 11071065	3^	BLOOD	Anaemia/ ANEMIA	2	09NOV2020	75/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1109 11091204	3^	INFEC	Appendicitis/ ACUTE APPENDICITIS	1	17AUG2020	7/17	4	No	O	NA/TC	R (02SEP2020)	Y/N
			Peritoneal abscess/ Peritoneal Abscess	1	17AUG2020	7/17	4	No	O	NA/TC	R (02SEP2020)	Y/N
16-55/ C4591001 1109 11091448	3^	NERV	Hemiplegic migraine/ Hemiplegic Migraine	2	20OCT2020	23/C	4	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1111 11111130	3^	NERV	Subarachnoid haemorrhage/ Subarachnoid hemorrhage	1	26AUG2020	9/9	2	No	O	NA/TC/TCN	R (03SEP2020)	Y/N
16-55/ C4591001 1116 11161059	3^	GASTR	Obstructive pancreatitis/ Gall Stone Pancreatitis	1	13SEP2020	14/6	3	No	O	NA/TC/TCN	R (18SEP2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		HEPAT	Bile duct stone/ Cholelithiasis	1	13SEP2020	14/7	3	No	O	NA/TC/TCN	R (19SEP2020)	Y/N
16-55/ C4591001 1117 11171036	3^	NERV	Syncope/ Syncopal Episode	1	26AUG2020	7/5	4	No	O	NA	R (30AUG2020)	Y/N
		PSYCH	Suicidal ideation/ Suicidal ideation	1	27AUG2020	8/4	4	No	O	NA/TC	R (30AUG2020)	Y/N
16-55/ C4591001 1117 11171186	3^	PSYCH	Suicide attempt/ SUICIDAL IDEATION WITH ATTEMPT	1	19OCT2020	14/8	3	No	O	NA/TC/TCN/W	R (26OCT2020)	Y/N
16-55/ C4591001 1124 11241106	3^	CARD	Acute myocardial infarction/ ST elevation myocardial infarction	2	27SEP2020	12/17	4	No	O	NA	R (13OCT2020)	Y/N
16-55/ C4591001 1128 11281103	3^	INFEC	Escherichia urinary tract infection/ Escherichia coli urinary tract infection	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N
		INV	Blood potassium decreased/ Low potassium	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N
		RENAL	Nephrolithiasis/ Kidney Stones	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N
16-55/ C4591001 1140 11401009	3^	IMMUN	Anaphylactic reaction/ Anaphylaxis Status Post Bee Sting	2	28AUG2020	9/1	4	No	O	NA/TC	R (28AUG2020)	Y/N
16-55/ C4591001	3^	PSYCH	Suicidal ideation/ Suicidal Ideation	1	19AUG2020	8/3	4	No	O	NA/TC	R (21AUG2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1142 11421084												
16-55/ C4591001 1145 11451063	3^	NERV	Paraesthesia/ Paresthesias of Skin	1	21SEP2020	22/8	3	No	CD	NA/TC	R (28SEP2020)	Y/N
16-55/ C4591001 1146 11461200	3^	CARD	Bradycardia/ Acute Bradycardia	2	27SEP2020	3/2	3	No	O	NA/TC	R (28SEP2020)	Y/N
		NERV	Loss of consciousness/ Loss of consciousness	2	27SEP2020	3/3	2	No	O	NA	R (29SEP2020)	Y/N
16-55/ C4591001 1150 11501001	3^	GASTR	Pancreatitis/ Worsening Pancreatitis	1	21AUG2020	5/34	3	No	O	NA	R (23SEP2020)	Y/N
16-55/ C4591001 1152 11521085	3^	GENRL	Unevaluable event/ Unknown of Unknown Origin	1	26AUG2020	8/1	4	No	O	P/W	F (26AUG2020)	Y/N
16-55/ C4591001 1156 11561006	3^	VASC	Deep vein thrombosis/ DEEP VEIN THROMBOSIS	1	31AUG2020	12/10	3	No	O	NA/TC	R (09SEP2020)	Y/N
16-55/ C4591001 1156 11561007	3^	PREG	Abortion spontaneous incomplete/ INCOMPLETE SPONTANEOUS ABORTION	2	04OCT2020	25/4	3	No	O	NA/TCN	R (07OCT2020)	Y/N
16-55/ C4591001	3^	HEPAT	Cholecystitis acute/ Acute Cholecystitis	1	21AUG2020	5/2	3	No	O	NA/TC/TCN	R (22AUG2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1167 11671009												
16-55/ C4591001 1167 11671175	3^	NERV	Cerebrovascular accident/ Cerebrovascular accident	2	21OCT2020	23/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1178 11781107	3^	BLOOD	Lymphadenopathy/ right axilla lymphadenopathy	1	16SEP2020	13/C	2	Yes		P/TC	N	Y/N
16-55/ C4591001 1223 12231166	3^	VASC	Hypertensive urgency/ hypertensive urgency	2	28OCT2020	22/9	2	No	O	NA/TC	R (05NOV2020)	Y/N
16-55/ C4591001 1226 12261067	3^	RENAL	Nephrolithiasis/ Worsening of nephrolithiasis	2	09NOV2020	70/3	3	No	O	NA/TC	R (11NOV2020)	Y/N
16-55/ C4591001 1226 12261137	3^	INJ&P	Forearm fracture/ Right forearm fracture	2	20SEP2020	18/10	3	No	O	NA/TC/TCN	R (29SEP2020)	Y/N
16-55/ C4591001 1226 12261282	3^	INFEC	Appendicitis/ Appendicitis	2	01OCT2020	22/3	3	No	O	NA/TC/TCN	R (03OCT2020)	Y/N
16-55/ C4591001 1226 12261300	3^	RENAL	Renal colic/ Renal colic	1	29AUG2020	10/2	4	No	O	NA/TC/TCN	R (30AUG2020)	Y/N
16-55/ C4591001	3^	INJ&P	Cervical vertebral fracture/	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1226 12261571			Fracture of the fourth cervical vertebra									
			Road traffic accident/ hit by motorcycle	2	21OCT2020	27/1	3	No	O	NA	R (21OCT2020)	Y/N
			Spinal cord injury cervical/ Cervical spinal cord contusion	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N
		NERV	Subarachnoid haemorrhage/ Subarachnoid hemorrhage	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N
		RENAL	Subcapsular renal haematoma/ Peri-renal hematoma	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N
16-55/ C4591001 1226 12261745	3^	NEOPL	Leydig cell tumour of the testis/ Leydig cell tumor in left testicle	1	23SEP2020	8/15	2	No	O	NA	R (07OCT2020)	Y/N
16-55/ C4591001 1226 12261769	3^	NERV	Idiopathic intracranial hypertension/ idiopathic intracranial hypertension	2	22OCT2020	16/9	3	No	O	NA/TC/TCN	R (30OCT2020)	Y/N
		INFEC	Postoperative wound infection/ surgical site infection	2	03NOV2020	28/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1226 12262089	3^	INFEC	Urinary tract infection/ Urinary tract infection	1	18OCT2020	13/5	3	No	O	NA/TC	R (22OCT2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C4591001 1231 12311205	3^	INJ&P	Ulna fracture/ Left arm olecranon fracture	2	17SEP2020	15/C	3	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1231 12311281	3^	INFEC	Appendicitis/ acute appendicitis	2	18SEP2020	15/19	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N
16-55/ C4591001 1231 12311315	3^	NEOPL	Malignant melanoma/ Pigmented ephitelioid melanoma of the vagina	2	25SEP2020	23/C	2	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1231 12311352	3^	GENRL	Influenza like illness/ Flu like syndrome	1	20AUG2020	6/3	3	No	O	NA	R (22AUG2020)	Y/N
16-55/ C4591001 1231 12311711	3^	INFEC	Urosepsis/ Urosepsis	2	15SEP2020	9/8	3	No	O	NA/TC	R (22SEP2020)	Y/N
16-55/ C4591001 1231 12311766	3^	HEPAT	Biliary colic/ biliary colic	2	30OCT2020	54/5	3	No	O	NA/TC	R (03NOV2020)	Y/N
16-55/ C4591001 1231 12311834	3^	INJ&P	Foot fracture/ Hallux fracture and second toe of the right foot	2	16SEP2020	10/35	3	No	O	NA/TC/TCN	R (20OCT2020)	Y/N
16-55/ C4591001 1231 12311844	3^	METAB	Hypoglycaemia/ severe hipoglycemia	2	16OCT2020	40/1	3	No	O	NA	R (16OCT2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C4591001 1231 12312390	3^	MUSC	Osteochondritis/ Osteochondritis	1	05SEP2020	18/2	2	No	O	NA	R (06SEP2020)	Y/N
16-55/ C4591001 1231 12312576	3^	RENAL	Renal colic/ Renal colic	2	05NOV2020	58/C	3	No	O	NA/TC	N	Y/N
16-55/ C4591001 1231 12312577	3^	NEOPL	Metastases to central nervous system/ Brain metastasis	1	28AUG2020	9/C	1	No	O	P/TC	N	Y/N
16-55/ C4591001 1231 12312593	3^	CARD	Acute coronary syndrome/ Acute coronary syndrome without ST-T segment elevation	2	16SEP2020	6/4	2	No	O	NA/TC	R (19SEP2020)	Y/N
16-55/ C4591001 1231 12312854	3^	CARD	Arrhythmia supraventricular/ Arrhythmia supraventricular	2	17SEP2020	7/3	4	No	O	NA/TC/TCN	R (19SEP2020)	Y/N
16-55/ C4591001 1231 12312868	3^	NERV	Syncope/ syncope	2	08OCT2020	1/1	3	No	O	NA/TCN	R (08OCT2020)	Y/N
16-55/ C4591001 1231 12312914	3^	CARD	Atrioventricular block second degree/ Second degree AV block (Mobitz II)	2	10NOV2020	58/C	2	No	O	NA	RG	Y/N
16-55/ C4591001	3^	INFEC	Suspected COVID-19/ Suspected COVID-19 Illness	2	09SEP2020	1/6	3	No	O	NA/TC	R (14SEP2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1231 12312982												
16-55/ C4591001 1231 12313193	3^	RENAL	Urinary bladder polyp/ Bladder polyp	2	18SEP2020	9/C	1	No	O	NA/TCN	RG	Y/N
16-55/ C4591001 1231 12313653	3^	NERV	Ischaemic stroke/ Ischemic Stroke	2	06NOV2020	55/C	3	No	O	NA	RG	Y/N
16-55/ C4591001 1231 12314407	3^	INJ&P	Multiple injuries/ Polytrauma	2	20SEP2020	5/C	3	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1231 12314833	3^	INFEC	Appendicitis/ appendicitis	2	16OCT2020	29/9	3	No	O	NA/TC/TCN	R (24OCT2020)	Y/N
		INFEC	Abdominal abscess/ Intra-abdominal Abscess	2	29OCT2020	42/C	3	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1231 12315291	3^	EYE	Choroidal neovascularisation/ Myopic choroidal neovascular membrane of the left eye	1	06SEP2020	9/C	2	No	O	NA	N	Y/N
16-55/ C4591001 1231 12315473	3^	CARD	Angina unstable/ Unstable Angina Pectoris	2	14OCT2020	26/3	3	No	O	NA/TCN	R (16OCT2020)	Y/N
16-55/ C4591001	3^	REPRO	Breast hyperplasia/ Atypical intraductal hyperplasia in left breast	2	29SEP2020	21/2	2	No	O	NA/TC	R (30SEP2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1241 12411206												
16-55/ C4591001 1241 12411279	3^	PREG	Retained products of conception/ RETAINED PRODUCTS OF CONCEPTION	1	14OCT2020	57/1	3	No	O	NA/TC	R (14OCT2020)	Y/N
16-55/ C4591001 1247 12471121	3^	INJ&P	Flail chest/ Flail Chest	2	30OCT2020	10/15	3	No	O	NA/TC/TCN/W	R (13NOV2020)	Y/N
16-55/ C4591001 1261 12611006	3^	INFEC	Abscess/ Lip Abscess	2	23SEP2020	7/9	3	No	O	NA/TC/TCN	R (01OCT2020)	Y/N
			Cellulitis/ Lip cellulitis	2	23SEP2020	7/9	3	No	O	NA/TC	R (01OCT2020)	Y/N
		IMMUN	Drug hypersensitivity/ Hypersensitivity to antibiotics	2	26SEP2020	10/2	3	No	CD	NA/TC	R (27SEP2020)	Y/N
16-55/ C4591001 1265 12651101	3^	METAB	Hypoglycaemia/ Hypoglycemia	1	12SEP2020	2/2	3	No	CD	NA/TC	R (13SEP2020)	Y/N
16-55/ C4591001 1270 12701069	3^	INFEC	Appendicitis/ APPENDICITIS	1	20SEP2020	17/3	3	No	O	NA/TC/TCN	R (22SEP2020)	Y/N
16-55/ C4591001 4444 44441007	3^	INJ&P	Procedural haemorrhage/ Intraoperative hemorrhage during an	1	03OCT2020	13/5	3	No	O	NA/TC	R (07OCT2020)	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C4591001 4444 44441249	3^	UNC	elective laparoscopic ovarian cystectomy JAMMED RIGHT INGUINAL HERNIA@@/ Jammed Right inguinal hernia	1	05OCT2020	15/18	3	No	O	NA/TC/TCN	R (22OCT2020)	Y/N
16-55/ C4591001 4444 44441748	3^	GASTR	Oesophageal food impaction/ esophageal impaction with food	1	28SEP2020	6/2	3	No	O	NA/TCN	R (29SEP2020)	Y/N
>55/ C4591001 1003 10031113	2^	RESP	Interstitial lung disease/ worsening of interstitial lung disease	2	17OCT2020	59/C	4	No	O	NA/TC/TCN	RG	Y/N
		MUSC	Scleroderma/ possible scleroderma	2	20OCT2020	62/C	3	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001 1003 10031149	3^	GASTR	Small intestinal obstruction/ small bowel obstruction	1	08AUG2020	4/3	4	No	O	NA/TC/TCN	R (10AUG2020)	Y/N
>55/ C4591001 1005 10051069	3^	NEOPL	Breast cancer/ LEFT BREAST CANCER	2	04SEP2020	3/C	1	No	O	NA	N	Y/N
>55/ C4591001 1006 10061020	3^	CARD	Coronary artery occlusion/ CORONARY ARTERY OCCLUSION	1	25AUG2020	14/3	4	No	O	P/TC/TCN/W	R (27AUG2020)	Y/N
>55/ C4591001	3^	CARD	Atrial fibrillation/ ATRIAL	2	06OCT2020	22/7	2	No	CD	NA/TC/TCN	R (12OCT2020)	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1006 10061098			FIBRILLATION INTERMITTENT									
>55/ C4591001 1007 10071101	2^	CARD	Cardiac arrest/ Cardiac Arrest	2	18OCT2020	60/4	4	No	O	NA/W	F (21OCT2020)	Y/N
>55/ C4591001 1008 10081184	3^	NEOPL	Prostate cancer/ Prostate cancer	2	30SEP2020	7/C	2	No	O	NA	N	Y/N
>55/ C4591001 1009 10091135	3^	NEOPL	Intraductal proliferative breast lesion/ Right Breast Ductal Carcinoma In Situ	1	02SEP2020	3/C	1	No	O	NA	N	Y/N
>55/ C4591001 1011 10111029	3^	INFEC	Appendicitis perforated/ Perforated Appendicitis	2	12SEP2020	13/4	3	No	O	NA/TC/TCN	R (15SEP2020)	Y/N
		INFEC	Peritonitis/ Feculant Peritonitis	2	14SEP2020	15/5	3	No	O	NA/TC/TCN	R (18SEP2020)	Y/N
>55/ C4591001 1013 10131176	3^	GASTR	Abdominal adhesions/ abdominal adhesions	1	29AUG2020	17/2	3	No	O	NA/TC	R (30AUG2020)	Y/N
			Small intestinal obstruction/ SMALL BOWEL OBSTRUCTION	1	29AUG2020	17/2	2	No	O	NA/TCN	R (30AUG2020)	Y/N
		RESP	Acute respiratory failure/ acute hypoxic respiratory failure	1	30AUG2020	18/13	3	No	O	NA	R (11SEP2020)	Y/N

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			Pneumonia aspiration/ ASPIRATION PNEUMONIA	1	30AUG2020	18/18	2	No	O	NA/TCN	R (16SEP2020)	Y/N
>55/ C4591001 1013 10131517	3^	CARD	Myocardial infarction/ MYOCARDIAL INFARCTION	2	08NOV2020	40/3	3	No	O	NA	R (10NOV2020)	Y/N
>55/ C4591001 1018 10181132	3^	INV	Cardiac stress test abnormal/ CARDIAC STRESS TEST ABNORMAL, HOSPITALIZED	2	08SEP2020	8/C	3	No	O	NA	N	Y/N
>55/ C4591001 1019 10191010	3^	GASTR	Diarrhoea/ Diarrhea	1	27AUG2020	17/3	4	No	O	NA	R (29AUG2020)	Y/N
>55/ C4591001 1019 10191037	3^	GENRL	Asthenia/ Weakness	2	27OCT2020	54/C	2	No	O	NA	UNK	Y/N
>55/ C4591001 1019 10191146	3^	NEOPL	Hepatic cancer metastatic/ poorly differentiated carcinoma metastatic to liver, unknown primary	2	27OCT2020	36/C	3	No	O	NA	N	Y/N
>55/ C4591001 1019 10191229	3^	INJ&P	Road traffic accident/ Motor Vehicle Collision	2	05NOV2020	22/C	4	No	O	NA	UNK	Y/N
>55/ C4591001	3^	NERV	Cerebrovascular accident/ Stroke (CVA)	2	02NOV2020	33/C	3	No	O	NA	RG	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1021 10211190												
>55/ C4591001 1027 10271054	3^	NEOPL	Acute myeloid leukaemia/ Acute Myeloid Leukemia	2	08NOV2020	58/C	3	No	O	NA	N	Y/N
>55/ C4591001 1038 10381101	3^	NERV	Ischaemic stroke/ Acute Ischemic Stroke	2	04OCT2020	7/3	2	No	O	NA	R (06OCT2020)	Y/N
>55/ C4591001 1042 10421166	3^	NERV	Subarachnoid haemorrhage/ SUBARACHNOID HEMORRAGE	1	03SEP2020	9/C	3	No	O	NA/TC	RG	Y/N
>55/ C4591001 1044 10441093	3^	INJ&P	Overdose/ Heroin Overdose	2	23OCT2020	26/2	4	No	O	NA/TC	R (24OCT2020)	Y/N
>55/ C4591001 1047 10471114	3^	NERV	Cerebrovascular accident/ Stroke	2	18OCT2020	26/C	3	No	O	NA	RG	Y/N
>55/ C4591001 1054 10541173	3^	CARD	Aortic valve incompetence/ acute severe aortic insufficiency	2	28OCT2020	20/C	4	No	O	NA/TC/TCN	N	Y/N
		NERV	Subarachnoid haemorrhage/ subarachnoid hemorrhage	2	05NOV2020	28/C	3	No	O	NA/TC/TCN	N	Y/N
>55/ C4591001	3^	INFEC	Appendicitis perforated/ Perforated appendicitis	1	31AUG2020	1/17	3	No	O	NA/TC/TCN	R (16SEP2020)	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1055 10551153 >55/ C4591001 1057 10571052	3^	INFEC	Pneumonia/ PNEUMONIA	2	20SEP2020	12/15	2	No	O	NA/TC	R (04OCT2020)	Y/N
>55/ C4591001 1071 10711023	3^	CARD	Coronary artery disease/ WORSENING coronary artery disease	1	23AUG2020	12/C	2	No	O	P/TCN/W	N	Y/N
>55/ C4591001 1071 10711169	3^	INJ&P	Alcohol poisoning/ ACUTE ALCOHOL INTOXICATION	1	02OCT2020	18/14	2	No	O	P/W	R (15OCT2020)	Y/N
>55/ C4591001 1072 10721007	3^	NERV	Transient ischaemic attack/ Transient Ischaemic Attack	1	04SEP2020	19/6	2	No	O	NA/TC/TCN	R (09SEP2020)	Y/N
>55/ C4591001 1079 10791228	3^	EYE	Retinal artery occlusion/ Central Retinal Artery Occlusion	2	29SEP2020	1/C	1	No	O	NA	N	Y/N
>55/ C4591001 1079 10791246	3^	NERV	Cerebrovascular accident/ CVA	2	22OCT2020	28/5	2	No	O	NA	R (26OCT2020)	Y/N
>55/ C4591001 1080 10801013	3^	MUSC	Osteoarthritis/ Osteoarthritis of the knee	2	26OCT2020	56/1	3	No	O	NA/TC/TCN	R (26OCT2020)	Y/N
		GASTR	Gastrointestinal disorder/ Bowel Problems	2	31OCT2020	61/C	3	No	O	NA/TC/TCN	N	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C4591001 1080 10801152	3^	METAB	Fluid retention/ Worsening of WATER RETENTION in lower extremities	1	16SEP2020	13/3	3	No	O	NA/TC	R (18SEP2020)	Y/N
		VASC	Hypertension/ Worsening of HYPERTENSION	1	16SEP2020	13/3	3	No	O	NA/TC	R (18SEP2020)	Y/N
>55/ C4591001 1081 10811026	3^	NEOPL	Borderline serous tumour of ovary/ Serous borderline tumor of left ovary	2	11OCT2020	40/6	3	No	O	NA/TC/TCN	R (16OCT2020)	Y/N
>55/ C4591001 1081 10811110	3^	INFEC	Empyema/ loculated empyema	2	11OCT2020	26/C	3	No	O	NA/TC	RG	Y/N
			Pneumonia/ Right lower lobe pneumonia	2	11OCT2020	26/C	3	No	O	NA/TC	RG	Y/N
>55/ C4591001 1082 10821076	3^	HEPAT	Cholelithiasis/ cholelithiasis	1	13AUG2020	7/3	3	No	O	NA/TCN	R (15AUG2020)	Y/N
>55/ C4591001 1082 10821094	3^	METAB	Diabetes mellitus/ diabetes	2	05NOV2020	66/C	1	No	O	NA/TC	N	Y/N
>55/ C4591001 1084 10841219	3^	REPRO	Ovarian cyst/ Left ovarian cyst, benign tumor	1	24AUG2020	8/27	2	No	O	NA/TC/TCN	R (19SEP2020)	Y/N
			Uterine prolapse/ Prolapsed uterus	1	24AUG2020	8/27	2	No	O	NA/TC/TCN	R (19SEP2020)	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C4591001 1085 10851216	3^	INJ&P	Lower limb fracture/ Left leg fracture of tibia/fibula	2	17OCT2020	25/2	1	No	O	NA/TC/TCN	R (18OCT2020)	Y/N
>55/ C4591001 1087 10871029	3^	NERV	Toxic encephalopathy/ Acute Toxic Metabolic Encephalopathy	2	28OCT2020	64/9	3	No	CD	NA/TC	R (05NOV2020)	Y/N
>55/ C4591001 1087 10871070	3^	CARD	Acute coronary syndrome/ ACUTE CORONARY SYNDROME	2	08SEP2020	8/3	3	No	O	NA/TC/TCN	R (10SEP2020)	Y/N
>55/ C4591001 1087 10871121	3^	GASTR	Gastrointestinal haemorrhage/ GI Bleed	1	07SEP2020	20/3	3	No	O	P/TC/TCN/W	R (09SEP2020)	Y/N
>55/ C4591001 1087 10871150	3^	INFEC	Pharyngitis streptococcal/ STREP THROAT	1	01SEP2020	12/5	3	No	O	NA/TC	R (05SEP2020)	Y/N
>55/ C4591001 1087 10871228	3^	CARD	Cardiac failure congestive/ Worsening of Chronic Congestive Heart Failure	1	03SEP2020	9/6	3	No	O	P/TC/W	R (08SEP2020)	Y/N
>55/ C4591001 1089 10891150	3^	CARD	Atrial fibrillation/ Chronic atrial fibrillation with RVR'	2	04OCT2020	26/2	3	No	O	NA/TC/TCN	R (05OCT2020)	Y/N
>55/ C4591001 1090 10901300	3^	IMMUN	Anaphylactic shock/ anaphylactic shock	2	09OCT2020	19/1	4	No	O	NA/TC	R (09OCT2020)	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C4591001 1092 10921015	3^	CARD	Atrial fibrillation/ Arrhythmia atrial fibrillation	1	26AUG2020	8/2	2	No	O	NA/TC	R (27AUG2020)	Y/N
>55/ C4591001 1092 10921123	3^	GASTR	Abdominal pain upper/ Epigastric Pain	1	07OCT2020	37/2	3	No	O	NA/TC	R (08OCT2020)	Y/N
>55/ C4591001 1092 10921187	3^	CARD	Cardiac failure congestive/ Congestive heart failure	1	01OCT2020	17/3	2	No	O	NA/TC	R (03OCT2020)	Y/N
>55/ C4591001 1095 10951101	3^	RESP	Pulmonary embolism/ Pulmonary Embolism	2	30OCT2020	64/9	3	No	O	NA/TC	R (07NOV2020)	Y/N
>55/ C4591001 1095 10951107	3^	NERV	Dizziness/ Dizziness, secondary to Clonidine reaction	2	31AUG2020	5/3	2	No	O	NA	R (02SEP2020)	Y/N
		CARD	Tachyarrhythmia/ Suspected tachy- arrhythmia	2	08SEP2020	13/15	3	No	O	NA/TC	R (22SEP2020)	Y/N
>55/ C4591001 1095 10951180	3^	NERV	Dizziness/ Dizziness	2	05NOV2020	45/2	1	No	O	NA	R (06NOV2020)	Y/N
>55/ C4591001 1095 10951204	3^	NEOPL	Bladder cancer/ Bladder Cancer	2	02NOV2020	43/C	3	No	O	NA	N	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C4591001 1095 10951228	3^	UNC	SHORTNESS OF BREATH@@/ shortness of breath	2	13NOV2020	51/C	2	No	O	NA/TC	N	Y/N
>55/ C4591001 1096 10961044	3^	INV	Hepatic enzyme increased/ Elevated Liver Enzymes	2	21SEP2020	12/C	3	No	O	NA	N	Y/N
>55/ C4591001 1097 10971011	3^	INFEC	Pneumonia/ Pneumonia	2	20SEP2020	12/16	3	No	O	NA/TC	R (05OCT2020)	Y/N
>55/ C4591001 1097 10971017	3^	NERV	Encephalopathy/ Acute encephalopathy	2	18OCT2020	34/C	3	No	O	NA/TC	RG	Y/N
		SURG	Hospitalisation/ Hospitalization not otherwise specified.	2	13NOV2020	60/C	3	No	O	NA	N	Y/N
>55/ C4591001 1097 10971025	3^	CARD	Acute myocardial infarction/ Non-STEMI	2	15SEP2020	2/1	3	No	O	NA/TC/TCN	R (15SEP2020)	Y/N
>55/ C4591001 1097 10971061	3^	NERV	Uraemic encephalopathy/ Uremic encephalopathy	2	22OCT2020	36/4	3	No	O	NA/TC	RS (25OCT2020)	Y/N
		RENAL	Acute kidney injury/ Acute kidney injury	2	22OCT2020	36/4	3	No	CD	NA/TC	RS (25OCT2020)	Y/N
>55/ C4591001	3^	INFEC	Pneumonia/ Pneumonia	2	07OCT2020	15/C	3	No	O	NA/TC/TCN	RG	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1097 10971084												
>55/ C4591001 1098 10981024	3^	GENRL	Chest pain/ ChestPain	2	07OCT2020	14/3	1	No	O	NA/TC/TCN	R (09OCT2020)	Y/N
		INFEC	Pneumonia/ Community Acquired Pneumonia	2	07OCT2020	14/3	1	No	O	NA	R (09OCT2020)	Y/N
>55/ C4591001 1107 11071044	3^	HEPAT	Cholelithiasis/ CHOLELITHIASIS	2	11SEP2020	17/5	3	No	O	NA/TC/TCN	R (15SEP2020)	Y/N
>55/ C4591001 1109 11091111	3^	INFEC	Diverticulitis/ Diverticulitis flair-up	2	08NOV2020	78/6	4	No	O	NA/TC	R (13NOV2020)	Y/N
>55/ C4591001 1109 11091164	3^	VASC	Deep vein thrombosis/ Deep Vein Thrombosis	2	07SEP2020	15/C	4	No	O	NA/TC	RG	Y/N
>55/ C4591001 1109 11091276	3^	INFEC	Complicated appendicitis/ Acute appendicitis with necrosis	2	30SEP2020	22/3	4	No	O	NA/TC/TCN	R (02OCT2020)	Y/N
>55/ C4591001 1109 11091387	3^	MUSC	Osteoarthritis/ Worsening osteoarthritis of the right knee	2	14OCT2020	23/2	4	No	O	NA/TC/TCN	R (15OCT2020)	Y/N
>55/ C4591001	3^	RESP	Dyspnoea/ Shortness of breath	2	06NOV2020	14/C	4	No	O	NA/TC	RG	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1109 11091558 >55/ C4591001 1110 11101031	3^	METAB	Type 2 diabetes mellitus/ Diabetes Type 2	2	12NOV2020	80/C	4	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001 1111 11111095	3^	PSYCH	Mental disorder/ Undiagnosed Mental Disorder (not otherwise specified)	2	25SEP2020	25/C	2	No	O	NA	N	Y/N
>55/ C4591001 1111 11111109	3^	INFEC	Pyelonephritis/ Pyelonephritis	2	28SEP2020	25/5	2	No	O	NA/TC	R (02OCT2020)	Y/N
>55/ C4591001 1114 11141080	3^	INFEC	Staphylococcal infection/ MRSA infection Right Stump	1	12SEP2020	20/27	2	No	O	NA/TC	R (08OCT2020)	Y/N
>55/ C4591001 1116 11161045	3^	BLOOD	Thrombocytopenia/ Thrombocytopenia	2	27OCT2020	40/16	1	No	O	NA	R (11NOV2020)	Y/N
>55/ C4591001 1118 11181044	3^	UNC	BILATERAL PULMONARY EMBOLISM@@/ bilateral pulmonary embolism	2	11NOV2020	65/C	3	No	O	NA/TC	RG	Y/N
>55/ C4591001 1118 11181057	3^	INFEC	Diverticulitis/ Sigmoid diverticulitis	1	04SEP2020	18/15	3	No	O	NA/TC	R (18SEP2020)	Y/N

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Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C4591001 1118 11181074	3^	MUSC	Musculoskeletal chest pain/ chest wall pain	2	14SEP2020	4/51	2	No	O	NA/TC	RS (03NOV2020)	Y/N
>55/ C4591001 1127 11271023	3^	NEOPL	Invasive ductal breast carcinoma/ Malignant invasive ductal carcinoma left breast	2	05NOV2020	80/C	3	No	O	NA	N	Y/N
>55/ C4591001 1128 11281014	3^	INJ&P	Skin laceration/ Facial Lacerations	2	28AUG2020	2/24	2	No	O	NA/TCN	R (20SEP2020)	Y/N
>55/ C4591001 1129 11291074	3^	EAR	Vertigo/ Worsened Vertigo	1	21AUG2020	12/4	3	No	O	NA	R (24AUG2020)	Y/N
		EYE	Diplopia/ double vision	1	21AUG2020	12/2	3	No	O	NA	R (22AUG2020)	Y/N
>55/ C4591001 1129 11291138	3^	INFEC	Osteomyelitis/ osteomyelitis distal phalanx right 3rd toe	1	31AUG2020	7/27	3	No	O	NA/TC	R (26SEP2020)	Y/N
>55/ C4591001 1131 11311145	3^	NERV	Syncope/ Syncope	1	08OCT2020	31/6	3	No	O	NA/TC	R (13OCT2020)	Y/N
		VASC	Orthostatic hypotension/ Hypotension, orthostatic	1	18OCT2020	41/8	3	No	O	NA/TC	R (25OCT2020)	Y/N
>55/ C4591001	3^	CONG	Heart disease congenital/ congenital heart anomaly	2	02NOV2020	18/C	4	No	O	NA/TC	N	Y/N

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1131 11311222 >55/ C4591001 1133 11331006	3^	PSYCH	Bipolar disorder/ Worsening Bipolar Disorder	2	24AUG2020	4/12	3	No	O	NA/TC/TCN	R (04SEP2020)	Y/N
		INFEC	Urinary tract infection/ Urinary tract infection	2	05OCT2020	46/10	3	No	O	NA	R (14OCT2020)	Y/N
>55/ C4591001 1134 11341058	3^	GASTR	Intestinal obstruction/ Intestinal Obstruction	1	20AUG2020	9/15	3	No	O	NA/TCN	R (03SEP2020)	Y/N
>55/ C4591001 1134 11341250	3^	NEOPL	Adrenal gland cancer/ ADRENAL ADENOCARCINOMA	2	20OCT2020	27/C	4	No	O	NA/TC	N	Y/N
>55/ C4591001 1135 11351143	3^	HEPAT	Cholecystitis acute/ acute cholecystitis	2	14OCT2020	36/4	3	No	O	NA/TC/TCN	R (17OCT2020)	Y/N
>55/ C4591001 1140 11401002	2^	CARD	Coronary artery dissection/ Spontaneous coronary artery dissection	2	28AUG2020	12/1	4	No	O	NA	R (28AUG2020)	Y/N
>55/ C4591001 1140 11401078	3^	HEPAT	Cholecystitis acute/ Acute Cholecystitis	2	16SEP2020	20/15	4	No	O	NA/TC	R (30SEP2020)	Y/N
>55/ C4591001 1140 11401244	3^	GASTR	Small intestinal obstruction/ Small Bowel Obstruction	1	08SEP2020	7/13	3	No	O	NA	R (20SEP2020)	Y/N

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>55/ C4591001 1142 11421032	3^	VASC	Orthostatic hypotension/ Possible postural hypotension	2	31AUG2020	4/1	4	No	O	NA/TC	R (31AUG2020)	Y/N
>55/ C4591001 1142 11421044	3^	GASTR	Colitis/ Colitis	2	05SEP2020	8/C	3	No	O	NA/TC	RG	Y/N
>55/ C4591001 1142 11421247	3^	CARD	Ventricular arrhythmia/ Ventricular arrhythmias	2	14OCT2020	1/8	3	Yes		NA/TC	R (21OCT2020)	Y/N
>55/ C4591001 1145 11451056	3^	CARD	Tachycardia/ tachycardia	2	07OCT2020	21/2	3	No	O	NA	R (08OCT2020)	Y/N
>55/ C4591001 1146 11461161	3^	RESP	Interstitial lung disease/ Interstitial Pneumonitis	1	09SEP2020	10/1	2	No	O	NA	R (09SEP2020)	Y/N
>55/ C4591001 1146 11461264	3^	RESP	Pulmonary embolism/ Pulmonary Emboli	2	08NOV2020	26/C	2	No	O	NA/TC	N	Y/N
>55/ C4591001 1147 11471239	3^	REPRO	Ovarian mass/ Ovarian Mass	1	21SEP2020	12/C	2	No	O	NA/TCN	RG	Y/N
>55/ C4591001 1149 11491313	3^	RESP	Cough/ severe cough	2	01NOV2020	18/C	3	No	O	NA	RG	Y/N

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>55/ C4591001 1152 11521095	3^	PSYCH	Bipolar disorder/ worsening of bipolar disorder	2	29OCT2020	50/9	3	No	O	NA/TC	R (06NOV2020)	Y/N
>55/ C4591001 1152 11521260	3^	NEOPL	Malignant melanoma/ melanoma left shoulder	1	04SEP2020	5/35	3	No	O	NA/TC/TCN	R (08OCT2020)	Y/N
>55/ C4591001 1152 11521497	3^	NERV	Syncope/ vasovagal syncope	1	26OCT2020	20/	3	No	O	P/TC/TCN	UNK	Y/N
>55/ C4591001 1156 11561001	3^	INJ&P	Facial bones fracture/ FRACTURE OF ROOF OF RIGHT ORBITAL (GRADE 3)	2	06OCT2020	29/C	3	No	O	NA/TC	N	Y/N
			Traumatic intracranial haemorrhage/ TRAUMATIC INTRACRANIAL HEMORRHAGE	2	06OCT2020	29/C	3	No	O	NA/TC	RG	Y/N
		NERV	Subarachnoid haemorrhage/ SUBARACHNOID HEMORRHAGE	2	06OCT2020	29/12	4	No	O	NA/TC	R (17OCT2020)	Y/N
>55/ C4591001 1157 11571134	3^	NERV	Transient ischaemic attack/ Suspected Transient Ischemic Attack	2	27OCT2020	34/2	3	No	O	NA/TC	R (28OCT2020)	Y/N
>55/ C4591001	3^	INV	SARS-CoV-2 test positive/ SARS-COV-2 Positive	2	10NOV2020	7/C	3	No	O	NA	N	Y/N

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1161 11611029		INFEC	Pneumonia/ pneumonia	2	11NOV2020	8/C	3	No	O	NA	N	Y/N
>55/ C4591001 1162 11621059	3^	INFEC	Pneumonia/ pneumonia	2	03SEP2020	2/11	3	No	O	NA/TC	RS (13SEP2020)	Y/N
>55/ C4591001 1162 11621327	3^	VASC	Arteriosclerosis/ Atherosclerotic Disease	1	13SEP2020	4/1	4	No	O	NA/W	F (13SEP2020)	Y/N
>55/ C4591001 1167 11671085	3^	CARD	Angina unstable/ Unstable Angina Pectoris	2	20OCT2020	34/1	2	No	O	NA/TC/TCN	R (20OCT2020)	Y/N
>55/ C4591001 1170 11701217	3^	BLOOD	Neutropenia/ Neutropenia	2	01OCT2020	3/C	3	No	O	NA/TC/TCN	RG	Y/N
			Thrombocytopenia/ Thrombocytopenia	2	01OCT2020	3/C	2	No	O	NA	RG	Y/N
		INFEC	Cellulitis/ Cellulitis of left lower leg	2	01OCT2020	3/C	3	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001 1174 11741042	3^	RENAL	Nephrolithiasis/ nephrolithiasis	1	02OCT2020	17/5	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N

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>55/ C4591001 1178 11781015	3^	NERV	Transient global amnesia/ transient global amnesia	2	10OCT2020	26/1	3	No	O	NA	R (10OCT2020)	Y/N
>55/ C4591001 1178 11781025	3^	RENAL	Nephrolithiasis/ kidney stones	2	19SEP2020	4/5	3	No	O	NA/TC	R (23SEP2020)	Y/N
		INFEC	Pyelonephritis/ Pyelonephritis	2	03OCT2020	18/28	2	No	O	NA/TC	R (30OCT2020)	Y/N
>55/ C4591001 1178 11781048	3^	GASTR	Salivary gland calculus/ salivary gland stone	1	20SEP2020	21/C	2	No	O	NA/TC	RG	Y/N
>55/ C4591001 1178 11781138	3^	CARD	Myocardial infarction/ Myocardial infarction	2	08OCT2020	10/12	3	No	O	NA	R (19OCT2020)	Y/N
>55/ C4591001 1178 11781167	3^	HEPAT	Cholecystitis/ cholecystitis	2	09OCT2020	5/4	3	No	O	NA/TC/TCN	R (12OCT2020)	Y/N
>55/ C4591001 1223 12231097	3^	GENRL	Asthenia/ Generalized Weakness	2	12NOV2020	49/C	3	No	O	NA/TC	N	Y/N
>55/ C4591001 1223 12231159	3^	GASTR	Pancreatic mass/ Mass at Pancreatic Head	2	05NOV2020	36/C	3	No	O	NA/TC/TCN	N	Y/N

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>55/ C4591001 1223 12231182	3^	INFEC	Diverticulitis/ progression of diverticulitis	1	29SEP2020	14/C	3	No	O	NA/TC	RG	Y/N
		INFEC	Abscess intestinal/ Pericolonic Abscess	2	13OCT2020	5/C	4	No	O	NA/TC/TCN	N	Y/N
>55/ C4591001 1230 12301025	3^	NEOPL	Penile neoplasm/ Penile Intra Epithelial Neoplasia	2	06NOV2020	22/C	3	No	O	NA	N	Y/N
>55/ C4591001 1231 12311579	3^	GASTR	Gastritis/ Acute gastritis	2	17OCT2020	41/18	3	No	O	NA/TC/TCN	R (03NOV2020)	Y/N
>55/ C4591001 1231 12311946	3^	NERV	Syncope/ Syncope	2	11SEP2020	4/2	3	No	O	NA/TC	R (12SEP2020)	Y/N
>55/ C4591001 1231 12313621	3^	RESP	Pulmonary mass/ Right pulmonary nodule	2	24SEP2020	10/C	3	No	O	NA/TCN	UNK	Y/N
>55/ C4591001 1231 12313674	3^	RESP	Pneumonitis/ Non-specific Pneumonitis	2	29SEP2020	17/C	2	No	O	NA	RG	Y/N
>55/ C4591001 1231 12313783	3^	MUSC	Intervertebral disc protrusion/ Worsening lumbar disc herniation	1	10SEP2020	18/64	3	No	O	NA/TC/TCN	R (12NOV2020)	Y/N
>55/ C4591001	3^	NERV	Haemorrhagic stroke/ Hemorrhagic stroke	2	27SEP2020	15/2	4	No	O	NA/TC/W	F (28SEP2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1231 12313972												
>55/ C4591001 1231 12314001	3^	CARD	Acute coronary syndrome/ Acute coronary syndrome	2	08NOV2020	55/C	3	No	O	NA/TC/TCN	RG	Y/N
>55/ C4591001 1231 12314035	3^	CARD	Angina pectoris/ Angina Pectoris	2	20SEP2020	7/5	3	No	O	NA/TC/TCN	R (24SEP2020)	Y/N
>55/ C4591001 1231 12314216	3^	INFEC	Appendicitis/ Acute Appendicitis	1	05SEP2020	11/5	3	No	O	NA/TC/TCN	R (09SEP2020)	Y/N
>55/ C4591001 1231 12314898	3^	INFEC	Pneumonia/ community acquired pneumonia	2	03OCT2020	18/13	3	No	O	NA/TC/TCN	R (15OCT2020)	Y/N
>55/ C4591001 1231 12315632	3^	INFEC	Suspected COVID-19/ Probable COVID-19 illness	2	17OCT2020	29/C	4	No	O	NA/TC	N	Y/N
>55/ C4591001 1231 12315653	3^	NERV	Ischaemic stroke/ Ischemic stroke	2	12OCT2020	24/5	2	No	O	NA/TC	R (16OCT2020)	Y/N
>55/ C4591001 1241 12411643	3^	HEPAT	Cholecystitis/ Acute cholecystitis with cholelithiasis	2	24OCT2020	31/5	3	No	O	NA/TC	R (28OCT2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C4591001 1241 12411825	3^	INFEC	Pyelonephritis acute/ ACUTE PYELINEPHRITIS	2	02NOV2020	26/C	2	No	O	NA/TC	RG	Y/N
>55/ C4591001 1246 12461035	3^	GENRL	Chest pain/ Chest pain	2	10NOV2020	22/3	3	No	O	NA/TCN	R (12NOV2020)	Y/N
>55/ C4591001 1247 12471135	3^	NERV	Cerebral infarction/ Left Middle Cerebral Artery Infarct	1	21OCT2020	22/C	3	No	O	P/TC/TCN	N	Y/N
>55/ C4591001 1248 12481120	3^	NERV	Cerebrovascular accident/ Mild Stroke	1	23SEP2020	13/C	3	No	O	NA	RG	Y/N
>55/ C4591001 1248 12481163	3^	INFEC	Brain abscess/ Brain abscess	2	10OCT2020	6/C	4	No	O	NA/TCN	RG	Y/N
>55/ C4591001 1251 12511050	3^	VASC	Hypertension/ exacerbation of hypertension	1	04SEP2020	11/C	3	No	O	NA	RG	Y/N
>55/ C4591001 1260 12601037	3^	GASTR	Small intestinal obstruction/ small bowel obstruction	2	29OCT2020	38/8	3	No	O	NA/TC/TCN	R (05NOV2020)	Y/N
>55/ C4591001 1260 12601069	3^	INFEC	Appendicitis/ acute appendicitis	2	05OCT2020	12/3	2	No	O	NA/TC/TCN	R (07OCT2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C4591001 1270 12701057	3^	RESP	Pulmonary embolism/ Pulmonary embolism	1	23SEP2020	21/C	3	No	O	P/TC	RG	Y/N
16-55/ C4591001 1084 10841480	3	CARD	Acute myocardial infarction/ ST-segment elevated MYOCARDIAL INFARCTION	1	26OCT2020	13/1	2	No	O	NA/TC	R (26OCT2020)	Y/N
16-55/ C4591001 1140 11401306	3	NERV	Amnesia/ short term memory loss	1	07NOV2020	17/4	1	No	O	P/TC/TCN	R (10NOV2020)	Y/N
			Paraparesis/ working diagnosis was spastic paraparesis	1	07NOV2020	17/C	3	No	O	P/TC/TCN	RG	Y/N
16-55/ C4591001 1195 11951023	3	MUSC	Intervertebral disc protrusion/ herniated disc cervical vertebra	2	11NOV2020	8/C	1	No	O	NA	RG	Y/N
16-55/ C4591001 1221 12211007	3	INFEC	Meningitis bacterial/ Meningitis Bacterial	1	10NOV2020	26/C	3	No	O	NA/TC	N	Y/N
18-55/ C4591001 1003 10031065	1	NERV	Neuritis/ neuritis right arm	2	29JUL2020	15/C	3	No	O	NA	N	Y/N
>55/ C4591001 1005 10051293	3	CARD	Cardiac arrest/ CARDIAC ARREST	1	08NOV2020	21/1	4	No	O	NA/TC	R (08NOV2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		INJ&P	Overdose/ Overdose	1	08NOV2020	21/1	4	No	O	NA	R (08NOV2020)	Y/N
		RESP	Acute respiratory failure/ Acute Respiratory Failure	1	08NOV2020	21/C	4	No	O	NA	RG	Y/N
>55/ C4591001 1007 10071347	3	CARD	Atrial fibrillation/ atrial fibrillation	1	25OCT2020	11/2	3	No	O	NA/TC	R (26OCT2020)	Y/N
>55/ C4591001 1008 10081603	3	INFEC	Cellulitis/ CELLULITIS UPPER BACK	1	26OCT2020	13/8	3	No	O	NA/TC	R (02NOV2020)	Y/N
			Sepsis/ SEPSIS	1	26OCT2020	13/8	3	No	O	NA/TC	R (02NOV2020)	Y/N
>55/ C4591001 1057 10571327	3	INFEC	Peritonsillar abscess/ PENTONSILLAR ABSESS	1	22OCT2020	7/C	3	No	O	NA/TC/TCN	N	Y/N
>55/ C4591001 1066 10661350	3	CARD	Myocardial infarction/ myocardial infarction	1	03NOV2020	16/1	4	No	O	P/W	F (03NOV2020)	Y/N
>55/ C4591001 1111 11111193	3	GASTR	Pancreatitis acute/ Acute Pancreatitis	1	19OCT2020	5/3	3	No	O	NA/TC	R (21OCT2020)	Y/N
>55/ C4591001 1226 12262240	3	INJ&P	Femur fracture/ Fracture of the right femur	1	24OCT2020	9/6	3	No	O	NA/TCN	R (29OCT2020)	Y/N

16.2.7.5.4 Listing of Serious Adverse Events – All Subjects

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C4591001 1241 12412191	3 PSYCH	Disorientation/ Disorientation to clarify	2	09NOV2020	4/4	3	No	O	NA/TC	R (12NOV2020)	Y/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

Note: Preferred terms with @@ denote uncoded terms.

Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.

Note: ^ = Phase 2/3 38000 subject.

a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 18NOV2020 (06:01)

(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_1002_sae_all_p3

16.2.7.6.1 Listing of Adverse Events Leading to Discontinuation From Study – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group Administered)/ Subject	System Organ Class	Preferred	Investigator	Dose No.	Onset Date	Rel Day ^a / (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action:	Investigational Outcome (End Date)	SAE/ Imm (Yes/No)
				Term/ AE Text								Vaccine Dose/ Subject		
No subject meets the reporting criteria.														
Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions. Note: MedDRA (v23.0) coding dictionary applied.														
a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.														
b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.														
c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.														
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 29AUG2020 (09:41) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001_IA_P1/adae_1002_disc_p1														

16.2.7.6.1.1 Listing of Adverse Events Leading to Discontinuation Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group Administered)/ Subject	System Organ Class	Preferred	Dose No.	Onset Date	Rel Day ^{a/}	Dur (Days) ^b	Toxicity Vax Rel ^c	Cause of AE	Action:		SAE/ Imm (Yes/No)
				Term/ AE Investigator Text							Investigational Outcome (End Date)	Vaccine Dose/ Subject	
No subject meets the reporting criteria.													
Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions. Note: MedDRA (v23.0) coding dictionary applied.													
a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.													
b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.													
c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.													
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:26) Source Data: adae Table Generation: 21SEP2020 (10:01) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001_IA_P1_100/adae_1002_disc_100_p1													

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel	Toxicity Grade	Vax Rel ^c	Cause of AE	Action:		Outcome (End Date)	SAE/ Imm (Yes/No)
					Day ^a / Dur (Days) ^b				Investigational Vaccine Dose/ Subject			
18-55/ C4591001 1079 10791004	NEOPL	Adenocarcinoma gastric/ INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	1	20AUG2020	23/C	3	No	O: n/a	P/W	N	Y/N	

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.0) coding dictionary applied.

- a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.
- b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.
- c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:08) Source Data: adae Table Generation: 10SEP2020 (21:41)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adae_1002_disc_p2

16.2.7.6.4 Listing of Adverse Events Leading to Discontinuation – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C4591001 1012 10121163	3^	GENRL	Injection site dermatitis/ LEFT UPPER ARM DERMATITIS AT INJECTION SITE	1	11SEP2020	3/C	2	Yes		P/W	RG	N/N
16-55/ C4591001 1015 10151134	3^	EAR	Vertigo/ Worsening and continuing episode of Veritgo	1	28AUG2020	2/C	2	Yes		P	RG	N/N
16-55/ C4591001 1016 10161087	3^	GENRL	Injection site swelling/ injection site swelling	1	10AUG2020	1/10	3	Yes		P/TC	R (19AUG2020)	N/N
16-55/ C4591001 1027 10271105	3^	IMMUN	Allergy to vaccine/ Allergic Reaction to Study Vaccine	1	29AUG2020	2/14	2	Yes		P/TC	R (11SEP2020)	N/N
16-55/ C4591001 1055 10551145	3^	GASTR	Dysphagia/ Dysphagia	1	AUG2020	1/C	1	No	O	P	N	N/N
16-55/ C4591001 1079 10791004	2^	NEOPL	Adenocarcinoma gastric/ INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	1	20AUG2020	23/C	3	No	O	P/W	N	Y/N
16-55/ C4591001 1081 10811194	3^	GENRL	Death/ Death	2	01NOV2020	34/1	4	No	O	NA/W	F (01NOV2020)	Y/N
16-55/ C4591001	3^	CARD	Atrial fibrillation/ Paroxysmal Atrial	1	23AUG2020	20/17	3	No	O	P/TC/TCN	R (08SEP2020)	Y/N

16.2.7.6.4 Listing of Adverse Events Leading to Discontinuation – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1083 10831029			fibrillation with rapid ventricular response									
16-55/ C4591001 1083 10831060	3^	GASTR	Diverticular perforation/ Ruptured diverticulum	1	14AUG2020	9/11	4	No	O	P/TC/TCN	R (24AUG2020)	Y/N
16-55/ C4591001 1093 10931058	3^	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	28AUG2020	4/C		No	O	P	UNK	N/N
16-55/ C4591001 1095 10951141	3^	SKIN	Diabetic foot/ Diabetic Foot Ulcer R Foot	1	14SEP2020	20/C	1	No	O	NA/TCN/W	N	N/N
16-55/ C4591001 1095 10951173	3^	CARD	Acute myocardial infarction/ STEMI: ST elevation Myocardial Infarction	1	05SEP2020	8/5	4	No	O	P/TC/TCN	R (09SEP2020)	Y/N
16-55/ C4591001 1096 10961031	3^	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	14AUG2020	1/40		No	O	P	R (22SEP2020)	N/N
16-55/ C4591001 1117 11171186	3^	PSYCH	Suicide attempt/ SUICIDAL IDEATION WITH ATTEMPT	1	19OCT2020	14/8	3	No	O	NA/TC/TCN/W	R (26OCT2020)	Y/N
16-55/ C4591001 1122 11221026	3^	GASTR	Vomiting/ vomiting*		11SEP2020	/1	1	No	O	NA/W	R (11SEP2020)	N/N
		NERV	Presyncope/ pre-syncope*		11SEP2020	/1	1	No	O	NA/W	R (11SEP2020)	N/N

16.2.7.6.4 Listing of Adverse Events Leading to Discontinuation – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C4591001 1127 11271022	3^	PSYCH	Schizophrenia/ Schizophrenia	1	22AUG2020	24/C	1	No	O	P/TC	N	N/N
16-55/ C4591001 1133 11331170	3^	VASC	Hypertension/ Worsening of Hypertension	1	04SEP2020	22/C	2	No	O	P/TC	N	N/N
16-55/ C4591001 1134 11341153	3^	EYE	Eye pain/ right eye pain	1	25AUG2020	2/28	2	Yes		P	R (21SEP2020)	N/N
		GASTR	Abdominal discomfort/ upset stomach	1	25AUG2020	2/28	2	Yes		P/TC	R (21SEP2020)	N/N
			Diarrhoea/ diarrhea	1	25AUG2020	2/1	1	Yes		P	R (25AUG2020)	N/N
			Diarrhoea/ loose stools	1	25AUG2020	2/28	2	Yes		P	R (21SEP2020)	N/N
		GENRL	Fatigue/ fatigue	1	25AUG2020	2/28	2	Yes		P	R (21SEP2020)	N/N
		MUSC	Muscular weakness/ muscle weakness	1	25AUG2020	2/28	2	Yes		P	R (21SEP2020)	N/N
		NERV	Headache/ headache	1	25AUG2020	2/1	1	Yes		P	R (25AUG2020)	N/N
				1	25AUG2020	2/1	2	Yes		P/TC	R (25AUG2020)	N/N
16-55/ C4591001 1134 11341174	3^	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	26AUG2020	1/5	3	Yes		P	R (30AUG2020)	N/N

16.2.7.6.4 Listing of Adverse Events Leading to Discontinuation – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
		NERV	Headache/ WORSENING HEADACHE	1	27AUG2020	2/8	2	Yes		P/TC	R (03SEP2020)	N/N
		MUSC	Pain in extremity/ ARM PAIN (LEFT)	1	28AUG2020	3/6	3	Yes		P/TC	R (02SEP2020)	N/N
16-55/ C4591001 1152 11521085	3^	GENRL	Unevaluable event/ Unknown of Unknown Origin	1	26AUG2020	8/1	4	No	O	P/W	F (26AUG2020)	Y/N
16-55/ C4591001 1156 11561015	3^	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY*		21AUG2020	1/C		No	O	P	UNK	N/N
16-55/ C4591001 1163 11631059	3^	UNC	UPPER BODYRASH DUE TO VACCINE@@/ UPPER BODYRASH DUE TO VACCINE	1	08AUG2020	2/18	2	Yes		P/TC	R (25AUG2020)	N/N
16-55/ C4591001 1166 11661047	3^	NERV	Dizziness/ Dizziness	1	31AUG2020	1/1	1	Yes		P	R (31AUG2020)	N/N
16-55/ C4591001 1178 11781107	3^	BLOOD	Lymphadenopathy/ right axilla lymphadenopathy	1	16SEP2020	13/C	2	Yes		P/TC	N	Y/N
16-55/ C4591001 1224 12241065	3^	INV	Heart rate irregular/ Irregular Heart Rate	1	24AUG2020	1/18	2	Yes		P/W	R (10SEP2020)	N/N
16-55/ C4591001	3^	MUSC	Myalgia/ Muscle pain (shoulders)	1	18AUG2020	8/C	2	Yes		P/TC	RG	N/N

16.2.7.6.4 Listing of Adverse Events Leading to Discontinuation – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1226 12261072			and neck, on the right body side)									
16-55/ C4591001 1230 12301045	3^†	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	1	20OCT2020	22/C		No	O	P	UNK	N/N
16-55/ C4591001 1231 12311409	3^	GASTR	Vomiting/ vomits*		15AUG2020	/1	1	No	O	P/TCN/W	R (15AUG2020)	N/N
		NERV	Syncope/ Syncope*		15AUG2020	/1	2	No	O	P/TCN/W	R (15AUG2020)	N/N
16-55/ C4591001 1231 12311926	3^	NERV	Syncope/ Syncope*		18AUG2020	/1	2	No	O	NA/W	R (18AUG2020)	N/N
16-55/ C4591001 1231 12312577	3^	NEOPL	Metastases to central nervous system/ Brain metastasis	1	28AUG2020	9/C	1	No	O	P/TC	N	Y/N
16-55/ C4591001 1231 12312982	3^	PSYCH	Anxiety/ severe anxiety	2	23SEP2020	15/22	3	No	O	NA/W	R (14OCT2020)	N/N
16-55/ C4591001 1231 12315429	3^	GENRL	Injection site pain/ pain at injection site	1	30AUG2020	1/18	2	Yes		P/TC/W	R (16SEP2020)	N/Y
16-55/ C4591001 1231 12315441	3^	PSYCH	Depression/ depressive syndrome	1	10SEP2020	12/C	3	No	O	P/TC	RG	N/N

16.2.7.6.4 Listing of Adverse Events Leading to Discontinuation – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C4591001 1232 12321213	3^	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	01OCT2020	23/C		No	O	P	UNK	N/N
16-55/ C4591001 1232 12321293	3^	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	1	22OCT2020	22/C		No	O	P	RG	N/N
16-55/ C4591001 1241 12411279	3^	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	10SEP2020	23/35		No	O	P	R (14OCT2020)	N/N
16-55/ C4591001 1241 12411766	3^	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	1	09OCT2020	24/C		No	O	P	UNK	N/N
16-55/ C4591001 1246 12461025	3^	SKIN	Urticaria/ Intermittent urticaria generalised.	1	07OCT2020	10/27	2	Yes		P/TC	R (02NOV2020)	N/N
16-55/ C4591001 1247 12471121	3^	INJ&P	Flail chest/ Flail Chest	2	30OCT2020	10/15	3	No	O	NA/TC/TCN/W	R (13NOV2020)	Y/N
16-55/ C4591001 1248 12481218	3^	NERV	Syncope/ vasovagal syncope*		20SEP2020	/1	2	No	O	NA/W	R (20SEP2020)	N/N
16-55/ C4591001 1254 12541142	3^	INJ&P	Maternal exposure during pregnancy/ Maternal Exposure During Pregnancy	1	12SEP2020	1/C		No	O	P	UNK	N/Y

16.2.7.6.4 Listing of Adverse Events Leading to Discontinuation – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
16-55/ C4591001 4444 44441979	3^	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY*		05SEP2020	-20/C		No	O	P	UNK	N/N
>55/ C4591001 1005 10051214	3^	GENRL	Facial pain/ FACIAL TENDERNESS	1	06SEP2020	4/11	2	No	O	P/TC	R (16SEP2020)	N/N
			Swelling face/ FACIAL SWELLING	1	06SEP2020	4/11	2	No	O	P/TC	R (16SEP2020)	N/N
>55/ C4591001 1006 10061020	3^	CARD	Coronary artery occlusion/ CORONARY ARTERY OCCLUSION	1	25AUG2020	14/3	4	No	O	P/TC/TCN/W	R (27AUG2020)	Y/N
>55/ C4591001 1007 10071101	2^	CARD	Cardiac arrest/ Cardiac Arrest	2	18OCT2020	60/4	4	No	O	NA/W	F (21OCT2020)	Y/N
>55/ C4591001 1011 10111181	3^	GASTR	Paraesthesia oral/ Tingling around the mouth	1	08OCT2020	1/1	1	Yes		P	R (08OCT2020)	N/N
>55/ C4591001 1037 10371252	3^	UNC	FATIGUE@@/ FATIGUE	2	14OCT2020	2/2	1	Yes		P	R (15OCT2020)	N/N
>55/ C4591001 1054 10541186	3^	GASTR	Nausea/ nausea	1	23SEP2020	1/1	1	Yes		P	R (23SEP2020)	N/Y
		NERV	Dizziness/ lightheadedness	1	23SEP2020	1/1	1	Yes		P	R (23SEP2020)	N/Y

16.2.7.6.4 Listing of Adverse Events Leading to Discontinuation – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C4591001 1071 10711023	3^	CARD	Coronary artery disease/ WORSENING coronary artery disease	1	23AUG2020	12/C	2	No	O	P/TCN/W	N	Y/N
>55/ C4591001 1071 10711169	3^	INJ&P	Alcohol poisoning/ ACUTE ALCOHOL INTOXICATION	1	02OCT2020	18/14	2	No	O	P/W	R (15OCT2020)	Y/N
>55/ C4591001 1087 10871121	3^	GASTR	Gastrointestinal haemorrhage/ GI Bleed	1	07SEP2020	20/3	3	No	O	P/TC/TCN/W	R (09SEP2020)	Y/N
>55/ C4591001 1087 10871228	3^	CARD	Cardiac failure congestive/ Worsening of Chronic Congestive Heart Failure	1	03SEP2020	9/6	3	No	O	P/TC/W	R (08SEP2020)	Y/N
>55/ C4591001 1090 10901415	3^	NERV	Headache/ Headache	1	30SEP2020	14/21	2	No	O	P/TC	R (20OCT2020)	N/N
>55/ C4591001 1109 11091503	3^	GASTR	Abdominal pain upper/ ABDOMINAL PAIN RUQ	1	SEP2020	1/	3	No	O	P	R (30SEP2020)	N/N
>55/ C4591001 1112 11121118	3^	CARD	Tachycardia/ Tachycardia	1	12AUG2020	2/1	3	Yes		P/TC	R (12AUG2020)	N/N
>55/ C4591001 1112 11121255	3^	GENRL	Chills/ Chills	1	06OCT2020	1/2	2	Yes		P/TC	R (07OCT2020)	N/N

16.2.7.6.4 Listing of Adverse Events Leading to Discontinuation – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a /Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
			Pyrexia/ Fever	1	06OCT2020	1/2	2	Yes		P/TC	R (07OCT2020)	N/N
		NERV	Headache/ Headaches	1	06OCT2020	1/2	3	Yes		P/TC	R (07OCT2020)	N/N
>55/ C4591001 1120 11201127	3^	GASTR	Diarrhoea/ Diarrhea	1	12AUG2020	2/3	3	Yes		P/TC/W	R (14AUG2020)	N/N
>55/ C4591001 1140 11401035	3^	SKIN	Urticaria/ urticaria	1	13AUG2020	10/1	2	No	O	P/TC/W	R (13AUG2020)	N/N
>55/ C4591001 1142 11421111	3^	GASTR	Abdominal pain/ Abdominal Pain	1	26AUG2020	10/41	2	Yes		P	R (05OCT2020)	N/N
		SKIN	Night sweats/ Night sweats	1	29AUG2020	13/C	3	Yes		P	RG	N/N
>55/ C4591001 1145 11451076	3^	NERV	Parkinsonism/ parkinsonism	1	18SEP2020	15/C	1	No	O	P	N	N/N
>55/ C4591001 1152 11521359	3^	MUSC	Muscle spasms/ back muscle spasms	1	04SEP2020	1/2	3	No	O	P	R (05SEP2020)	N/N
>55/ C4591001 1152 11521476	3^	EAR	Deafness unilateral/ hearing loss right ear	1	14OCT2020	20/10	3	Yes		P	R (23OCT2020)	N/N

16.2.7.6.4 Listing of Adverse Events Leading to Discontinuation – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C4591001 1152 11521497	3^	NERV	Syncope/ vasovagal syncope	1	26OCT2020	20/	3	No	O	P/TC/TCN	UNK	Y/N
>55/ C4591001 1162 11621327	3^	VASC	Arteriosclerosis/ Atherosclerotic Disease	1	13SEP2020	4/1	4	No	O	NA/W	F (13SEP2020)	Y/N
>55/ C4591001 1224 12241012	3^	INJ&P	Ankle fracture/ Lateral Malleolus Fracture - left ankle	1	19AUG2020	7/C	2	No	O	P/TC/TCN/W	N	N/N
			Fall/ FALL	1	19AUG2020	7/1	2	No	O	NA/W	RS (19AUG2020)	N/N
		MUSC	Muscular weakness/ Diffuse weakness in extremities (Bilateral legs and Left arm)	1	19AUG2020	7/7	2	No	O	NA/W	RS (25AUG2020)	N/N
		NERV	Transient ischaemic attack/ Suspected TIA	1	19AUG2020	7/1	2	No	O	NA/W	RS (19AUG2020)	N/N
>55/ C4591001 1231 12313972	3^	NERV	Haemorrhagic stroke/ Hemorrhagic stroke	2	27SEP2020	15/2	4	No	O	NA/TC/W	F (28SEP2020)	Y/N
>55/ C4591001 1247 12471135	3^	NERV	Cerebral infarction/ Left Middle Cerebral Artery Infarct	1	21OCT2020	22/C	3	No	O	P/TC/TCN	N	Y/N
>55/ C4591001	3^	RESP	Pulmonary embolism/ Pulmonary embolism	1	23SEP2020	21/C	3	No	O	P/TC	RG	Y/N

16.2.7.6.4 Listing of Adverse Events Leading to Discontinuation – All Subjects

Age Group (Years)/ Subject	Phase	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
1270 12701057												
16-55/ C4591001 1087 10871557	3	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	24OCT2020	11/C		Yes		P	UNK	N/N
16-55/ C4591001 1090 10901507	3	SKIN	Urticaria/ Hives, upper chest	1	19OCT2020	4/4	2	Yes		P/TC	R (22OCT2020)	N/N
16-55/ C4591001 1140 11401306	3	NERV	Amnesia/ short term memory loss	1	07NOV2020	17/4	1	No	O	P/TC/TCN	R (10NOV2020)	Y/N
			Paraparesis/ working diagnosis was spastic paraparesis	1	07NOV2020	17/C	3	No	O	P/TC/TCN	RG	Y/N
16-55/ C4591001 1205 12051028	3	INV	Blood pressure increased/ Increasing of systolic and diastolic blood pressure*		30OCT2020	/1	2	No	O	NA/W	R (30OCT2020)	N/N
>55/ C4591001 1066 10661350	3	CARD	Myocardial infarction/ myocardial infarction	1	03NOV2020	16/1	4	No	O	P/W	F (03NOV2020)	Y/N
>55/ C4591001 1112 11121337	3	GASTR	Diarrhoea/ Diarrhea	1	22OCT2020	2/4	3	Yes		NA/TC/W	R (25OCT2020)	N/N
		GENRL	Fatigue/ Fatigue	1	22OCT2020	2/7	2	Yes		P	R (28OCT2020)	N/N

16.2.7.6.4 Listing of Adverse Events Leading to Discontinuation – All Subjects

Age Group (Years)/ Subject	System Organ Class Phase	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day ^a / Dur (Days) ^b	Toxicity Grade	Vax Rel ^c	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/ Imm (Yes/No)
>55/ C4591001 1120 11201408	3 PSYCH	Depression/ worsening of depression	1	29OCT2020	2/C	2	Yes		P	N	N/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

Note: Preferred terms with @@ denote uncoded terms.

Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.

Note: * = Prevaccination AE, ^ = Phase 2/3 38000 subject, † = HIV-positive subject.

a. Relative Day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): Relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adae Table Generation: 17NOV2020 (22:43)

(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adae_1002_disc_all_p3

16.2.7.7.1 Listing of Deaths – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject No.	Dose Rel Day^a	Sex	Date of Death	Age at Death (Years)	Primary Cause of Death	Secondary Cause(s) of Death
No subject meets the reporting criteria.									
Note: MedDRA (v23.0) coding dictionary applied. a. Relative Day (Rel Day) = date of death - date of last vaccination + 1. PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 31AUG2020 (22:52) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/cdl dth p1									

16.2.7.7.1.1 Listing of Deaths – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject No.	Dose Rel Day^a	Sex	Date of Death	Age at Death (Years)	Primary Cause of Death	Secondary Cause(s) of Death
No subject meets the reporting criteria.									
Note: MedDRA (v23.0) coding dictionary applied. a. Relative Day (Rel Day) = date of death - date of last vaccination + 1. PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 18SEP2020 (12:31) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001 IA P1 100/cdl dth 100 p1									

16.2.7.7.2 Listing of Deaths – Phase 2

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Sex	Date of Death	Age at Death (Years)	Primary Cause of Death	Secondary Cause(s) of Death
No subject meets the reporting criteria.								
<p>Note: MedDRA (v23.0) coding dictionary applied.</p> <p>a. Relative Day (Rel Day) = date of death - date of last vaccination + 1.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (14:18) Source Data: adsl Table Generation: 09SEP2020 (23:20) (Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/cdl_dth_p2</p>								

16.2.7.7.4 Listing of Deaths – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day ^a	Sex	Date of Death	Age at Death (Years)	Primary Cause of Death	Secondary Cause(s) of Death
16-55	C4591001 1081 10811194	2	34	F	01NOV2020	51	Death	
	C4591001 1152 11521085	1	8	F	26AUG2020	42	Death	
>55	C4591001 1007 10071101	2	63	F	21OCT2020	56	Cardiac arrest	
	C4591001 1066 10661350	1	16	M	03NOV2020	58	Myocardial infarction	
	C4591001 1162 11621327	1	4	M	13SEP2020	60	Arteriosclerosis	
	C4591001 1231 12313972	2	16	F	28SEP2020	61	Haemorrhagic stroke	

Note: MedDRA (v23.1) coding dictionary applied.

Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.

a. Relative Day (Rel Day) = date of death - date of last vaccination + 1.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:50) Source Data: adsl Table Generation: 19NOV2020 (02:11)

(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001 IA P3 2MPD2/cdl dth all p3

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
BNT162b1	65-85	20 µg	C4591001 1002 10021060	15JUN2020	1	1	E-diary	Redness	None/1		
				16JUN2020	2		E-diary		None		
				17JUN2020	3	Unscheduled clinical assessment		None			
				18JUN2020	4	E-diary		None			
				19JUN2020	5	E-diary		None			
				20JUN2020	6	E-diary		None			
				21JUN2020	7	E-diary		None			
				15JUN2020	1	E-diary	Swelling	None			
				16JUN2020	2	E-diary		None			
				17JUN2020	3	Unscheduled clinical assessment		None			
				18JUN2020	4	E-diary		None			
				19JUN2020	5	E-diary		None			

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
				20JUN2020		6	E-diary		None		
				21JUN2020		7	E-diary		None		
				15JUN2020		1	E-diary	Pain at the injection site	Mild		
				16JUN2020		2	E-diary		Mild		
				17JUN2020		3	Unscheduled clinical assessment		Mild	17JUN2020	3
				18JUN2020		4	E-diary		None		
				19JUN2020		5	E-diary		None		
				20JUN2020		6	E-diary		None		
				21JUN2020		7	E-diary		None		
				15JUN2020		1	E-diary	Fever (°C)	None/37.7		
				16JUN2020		2	E-diary		None/37.3		
				17JUN2020		3	Unscheduled clinical assessment		None/37.2		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary ^b	Stop Date ^c	Dur (Days) ^d
				18JUN2020		4	E-diary		None/37.1		
				19JUN2020		5	E-diary		None/37.2		
				20JUN2020		6	E-diary		None/37		
				21JUN2020		7	E-diary		None/36.7		
				15JUN2020		1	E-diary	Fatigue	None		
				16JUN2020		2	E-diary		None		
				17JUN2020		3	Unscheduled clinical assessment		None		
				18JUN2020		4	E-diary		None		
				19JUN2020		5	E-diary		None		
				20JUN2020		6	E-diary		None		
				21JUN2020		7	E-diary		None		
				15JUN2020		1	E-diary	Headache	None		
				16JUN2020		2	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				17JUN2020	3		Unscheduled clinical assessment		None		
				18JUN2020	4		E-diary		None		
				19JUN2020	5		E-diary		None		
				20JUN2020	6		E-diary		None		
				21JUN2020	7		E-diary		None		
				15JUN2020	1		E-diary	Chills	Mild		
				16JUN2020	2		E-diary		Mild		
				17JUN2020	3		Unscheduled clinical assessment		Mild	17JUN2020	3
				18JUN2020	4		E-diary		None		
				19JUN2020	5		E-diary		None		
				20JUN2020	6		E-diary		None		
				21JUN2020	7		E-diary		None		
				15JUN2020	1		E-diary	Vomiting	None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				16JUN2020		2	E-diary		None		
				17JUN2020		3	Unscheduled clinical assessment		None		
				18JUN2020		4	E-diary		None		
				19JUN2020		5	E-diary		None		
				20JUN2020		6	E-diary		None		
				21JUN2020		7	E-diary		None		
				15JUN2020		1	E-diary	Diarrhea	None		
				16JUN2020		2	E-diary		None		
				17JUN2020		3	Unscheduled clinical assessment		None		
				18JUN2020		4	E-diary		None		
				19JUN2020		5	E-diary		None		
				20JUN2020		6	E-diary		Mild	20JUN2020	1
				21JUN2020		7	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				15JUN2020	1		E-diary	New or worsened muscle pain	None		
				16JUN2020	2		E-diary		Severe		
				17JUN2020	3		Unscheduled clinical assessment		Severe	17JUN2020	2
				18JUN2020	4		E-diary		None		
				19JUN2020	5		E-diary		None		
				20JUN2020	6		E-diary		None		
				21JUN2020	7		E-diary		None		
				15JUN2020	1		E-diary	New or worsened joint pain	None		
				16JUN2020	2		E-diary		None		
				17JUN2020	3		Unscheduled clinical assessment		None		
				18JUN2020	4		E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
				19JUN2020		5	E-diary		None		
				20JUN2020		6	E-diary		None		
				21JUN2020		7	E-diary		None		
				15JUN2020		1	E-diary	Use of antipyretic or pain medication	No		
				16JUN2020		2	E-diary		Yes	16JUN2020	1
				18JUN2020		4	E-diary		No		
				19JUN2020		5	E-diary		No		
				20JUN2020		6	E-diary		No		
				21JUN2020		7	E-diary		No		
				07JUL2020	2	1	E-diary	Redness	None		
				08JUL2020		2	E-diary		None		
				09JUL2020		3	E-diary		None		
				10JUL2020		4	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
				11JUL2020		5	E-diary		None		
				12JUL2020		6	E-diary		None		
				13JUL2020		7	E-diary		None		
				07JUL2020		1	E-diary	Swelling	None		
				08JUL2020		2	E-diary		None		
				09JUL2020		3	E-diary		None		
				10JUL2020		4	E-diary		None		
				11JUL2020		5	E-diary		None		
				12JUL2020		6	E-diary		None		
				13JUL2020		7	E-diary		None		
				07JUL2020		1	E-diary	Pain at the injection site	None		
				08JUL2020		2	E-diary		None		
				09JUL2020		3	E-diary		None		
				10JUL2020		4	E-diary		None		
				11JUL2020		5	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary ^b	Stop Date ^c	Dur (Days) ^d
				12JUL2020		6	E-diary		None		
				13JUL2020		7	E-diary		None		
				07JUL2020		1	E-diary	Fever (°C)	None/36.8		
				08JUL2020		2	E-diary		None/37.6		
				09JUL2020		3	E-diary		None/36.6		
				10JUL2020		4	E-diary		None/36.8		
				11JUL2020		5	E-diary		None/36.9		
				12JUL2020		6	E-diary		None/37		
				13JUL2020		7	E-diary		None/37.6		
				07JUL2020		1	E-diary	Fatigue	None		
				08JUL2020		2	E-diary		None		
				09JUL2020		3	E-diary		None		
				10JUL2020		4	E-diary		None		
				11JUL2020		5	E-diary		None		
				12JUL2020		6	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
				13JUL2020		7	E-diary		None		
				07JUL2020		1	E-diary	Headache	None		
				08JUL2020		2	E-diary		None		
				09JUL2020		3	E-diary		None		
				10JUL2020		4	E-diary		None		
				11JUL2020		5	E-diary		None		
				12JUL2020		6	E-diary		None		
				13JUL2020		7	E-diary		None		
				07JUL2020		1	E-diary	Chills	Mild		
				08JUL2020		2	E-diary		Mild	08JUL2020	2
				09JUL2020		3	E-diary		None		
				10JUL2020		4	E-diary		None		
				11JUL2020		5	E-diary		None		
				12JUL2020		6	E-diary		None		
				13JUL2020		7	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				07JUL2020	1		E-diary	Vomiting	None		
				08JUL2020	2		E-diary		None		
				09JUL2020	3		E-diary		None		
				10JUL2020	4		E-diary		None		
				11JUL2020	5		E-diary		None		
				12JUL2020	6		E-diary		None		
				13JUL2020	7		E-diary		None		
				07JUL2020	1		E-diary	Diarrhea	None		
				08JUL2020	2		E-diary		None		
				09JUL2020	3		E-diary		None		
				10JUL2020	4		E-diary		None		
				11JUL2020	5		E-diary		None		
				12JUL2020	6		E-diary		None		
				13JUL2020	7		E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
				07JUL2020		1	E-diary	New or worsened muscle pain	None		
				08JUL2020		2	E-diary		None		
				09JUL2020		3	E-diary		None		
				10JUL2020		4	E-diary		None		
				11JUL2020		5	E-diary		None		
				12JUL2020		6	E-diary		None		
				13JUL2020		7	E-diary		None		
				07JUL2020		1	E-diary	New or worsened joint pain	None		
				08JUL2020		2	E-diary		None		
				09JUL2020		3	E-diary		None		
				10JUL2020		4	E-diary		None		
				11JUL2020		5	E-diary		None		
				12JUL2020		6	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
				13JUL2020		7	E-diary		None		
				07JUL2020		1	E-diary	Use of antipyretic or pain medication	No		
				08JUL2020		2	E-diary		Yes	08JUL2020	1
				09JUL2020		3	E-diary		No		
				10JUL2020		4	E-diary		No		
				11JUL2020		5	E-diary		No		
				12JUL2020		6	E-diary		No		
				13JUL2020		7	E-diary		No		
BNT162b2	18-55	30 µg	C4591001 1003 10031061	22JUN2020	1	1	E-diary	Redness	None		
				23JUN2020		2	E-diary		None		
				23JUN2020		2	Unscheduled clinical assessment		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				24JUN2020		3	E-diary		None		
				25JUN2020		4	E-diary		None		
				26JUN2020		5	E-diary		None		
				27JUN2020		6	E-diary		None		
				28JUN2020		7	E-diary		None		
				22JUN2020		1	E-diary	Swelling	None		
				23JUN2020		2	E-diary		None		
				23JUN2020		2	Unscheduled clinical assessment		None		
				24JUN2020		3	E-diary		None		
				25JUN2020		4	E-diary		None		
				26JUN2020		5	E-diary		None		
				27JUN2020		6	E-diary		None		
				28JUN2020		7	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				22JUN2020	1		E-diary	Pain at the injection site	Mild		
				23JUN2020	2		E-diary		Moderate		
				23JUN2020	2		Unscheduled clinical assessment		Severe	23JUN2020	2
				24JUN2020	3		E-diary		None		
				25JUN2020	4		E-diary		None		
				26JUN2020	5		E-diary		None		
				27JUN2020	6		E-diary		None		
				28JUN2020	7		E-diary		None		
				22JUN2020	1		E-diary	Fever (°C)	None/36.4		
				23JUN2020	2		E-diary		Mild/38		
				23JUN2020	2		Unscheduled clinical assessment		None/36.1	23JUN2020	1
				24JUN2020	3		E-diary		None/36.2		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				25JUN2020	4		E-diary		None/35.9		
				26JUN2020	5		E-diary		None/36.3		
				27JUN2020	6		E-diary		None/36.3		
				28JUN2020	7		E-diary		None/36.6		
				22JUN2020	1		E-diary	Fatigue	Moderate		
				23JUN2020	2		E-diary		Severe		
				23JUN2020	2		Unscheduled clinical assessment		Severe	23JUN2020	2
				24JUN2020	3		E-diary		None		
				25JUN2020	4		E-diary		None		
				26JUN2020	5		E-diary		None		
				27JUN2020	6		E-diary		None		
				28JUN2020	7		E-diary		None		
				22JUN2020	1		E-diary	Headache	None		
				23JUN2020	2		E-diary		Moderate		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				23JUN2020		2	Unscheduled clinical assessment		Severe	23JUN2020	1
				24JUN2020		3	E-diary		None		
				25JUN2020		4	E-diary		None		
				26JUN2020		5	E-diary		None		
				27JUN2020		6	E-diary		None		
				28JUN2020		7	E-diary		None		
				22JUN2020		1	E-diary	Chills	None		
				23JUN2020		2	E-diary		Moderate		
				23JUN2020		2	Unscheduled clinical assessment		Severe	23JUN2020	1
				24JUN2020		3	E-diary		None		
				25JUN2020		4	E-diary		None		
				26JUN2020		5	E-diary		None		
				27JUN2020		6	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				28JUN2020		7	E-diary		None		
				22JUN2020		1	E-diary	Vomiting	None		
				23JUN2020		2	E-diary		None		
				23JUN2020		2	Unscheduled clinical assessment		None		
				24JUN2020		3	E-diary		None		
				25JUN2020		4	E-diary		None		
				26JUN2020		5	E-diary		None		
				27JUN2020		6	E-diary		None		
				28JUN2020		7	E-diary		None		
				22JUN2020		1	E-diary	Diarrhea	None		
				23JUN2020		2	E-diary		None		
				23JUN2020		2	Unscheduled clinical assessment		None		
				24JUN2020		3	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				25JUN2020		4	E-diary		None		
				26JUN2020		5	E-diary		None		
				27JUN2020		6	E-diary		None		
				28JUN2020		7	E-diary		None		
				22JUN2020		1	E-diary	New or worsened muscle pain	None		
				23JUN2020		2	E-diary		Moderate		
				23JUN2020		2	Unscheduled clinical assessment		Severe	23JUN2020	1
				24JUN2020		3	E-diary		None		
				25JUN2020		4	E-diary		None		
				26JUN2020		5	E-diary		None		
				27JUN2020		6	E-diary		None		
				28JUN2020		7	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				22JUN2020	1		E-diary	New or worsened joint pain	None		
				23JUN2020	2		E-diary		Moderate		
				23JUN2020	2		Unscheduled clinical assessment		Severe	23JUN2020	1
				24JUN2020	3		E-diary		None		
				25JUN2020	4		E-diary		None		
				26JUN2020	5		E-diary		None		
				27JUN2020	6		E-diary		None		
				28JUN2020	7		E-diary		None		
				22JUN2020	1		E-diary	Use of antipyretic or pain medication	No		
				23JUN2020	2		E-diary		Yes	23JUN2020	1
				24JUN2020	3		E-diary		No		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				25JUN2020		4	E-diary		No		
				26JUN2020		5	E-diary		No		
				27JUN2020		6	E-diary		No		
				28JUN2020		7	E-diary		No		
				13JUL2020	2	1	E-diary	Redness	None		
				14JUL2020		2	E-diary		None		
				15JUL2020		3	E-diary		None		
				16JUL2020		4	E-diary		None		
				17JUL2020		5	E-diary		None		
				18JUL2020		6	E-diary		None		
				13JUL2020		1	E-diary	Swelling	None		
				14JUL2020		2	E-diary		None		
				15JUL2020		3	E-diary		None		
				16JUL2020		4	E-diary		None		
				17JUL2020		5	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary ^b	Stop Date ^c	Dur (Days) ^d
				18JUL2020		6	E-diary		None		
				13JUL2020		1	E-diary	Pain at the injection site	None		
				14JUL2020		2	E-diary		Mild	14JUL2020	1
				15JUL2020		3	E-diary		None		
				16JUL2020		4	E-diary		None		
				17JUL2020		5	E-diary		None		
				18JUL2020		6	E-diary		None		
				13JUL2020		1	E-diary	Fever (°C)	None/36.9		
				14JUL2020		2	E-diary		None/37.9		
				15JUL2020		3	E-diary		None/36.4		
				16JUL2020		4	E-diary		None/36.3		
				17JUL2020		5	E-diary		None/36.4		
				18JUL2020		6	E-diary		None/36.5		
				13JUL2020		1	E-diary	Fatigue	None		
				14JUL2020		2	E-diary		Moderate	14JUL2020	1

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				15JUL2020		3	E-diary		None		
				16JUL2020		4	E-diary		None		
				17JUL2020		5	E-diary		None		
				18JUL2020		6	E-diary		None		
				13JUL2020		1	E-diary	Headache	None		
				14JUL2020		2	E-diary		Moderate		
				15JUL2020		3	E-diary		Mild	15JUL2020	2
				16JUL2020		4	E-diary		None		
				17JUL2020		5	E-diary		None		
				18JUL2020		6	E-diary		None		
				13JUL2020		1	E-diary	Chills	None		
				14JUL2020		2	E-diary		Moderate	14JUL2020	1
				15JUL2020		3	E-diary		None		
				16JUL2020		4	E-diary		None		
				17JUL2020		5	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				18JUL2020		6	E-diary		None		
				13JUL2020		1	E-diary	Vomiting	None		
				14JUL2020		2	E-diary		None		
				15JUL2020		3	E-diary		None		
				16JUL2020		4	E-diary		None		
				17JUL2020		5	E-diary		None		
				18JUL2020		6	E-diary		None		
				13JUL2020		1	E-diary	Diarrhea	None		
				14JUL2020		2	E-diary		None		
				15JUL2020		3	E-diary		None		
				16JUL2020		4	E-diary		None		
				17JUL2020		5	E-diary		None		
				18JUL2020		6	E-diary		None		
				13JUL2020		1	E-diary	New or worsened muscle pain	None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary ^b	Stop Date ^c	Dur (Days) ^d
				14JUL2020		2	E-diary		Moderate	14JUL2020	1
				15JUL2020		3	E-diary		None		
				16JUL2020		4	E-diary		None		
				17JUL2020		5	E-diary		None		
				18JUL2020		6	E-diary		None		
				13JUL2020		1	E-diary	New or worsened joint pain	None		
				14JUL2020		2	E-diary		Moderate	14JUL2020	1
				15JUL2020		3	E-diary		None		
				16JUL2020		4	E-diary		None		
				17JUL2020		5	E-diary		None		
				18JUL2020		6	E-diary		None		
				13JUL2020		1	E-diary	Use of antipyretic or pain medication	No		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
Placebo	65-85	Placebo	C4591001 1003 10031083	14JUL2020	1	2	E-diary		Yes	14JUL2020	1
				15JUL2020	1	3	E-diary		No		
				16JUL2020	1	4	E-diary		No		
				17JUL2020	1	5	E-diary		No		
				18JUL2020	1	6	E-diary		No		
				01JUL2020	1	1	E-diary	Redness	None		
				02JUL2020	1	2	E-diary		None		
				03JUL2020	1	3	E-diary		None		
				04JUL2020	1	4	E-diary		None		
				05JUL2020	1	5	E-diary		None		
				06JUL2020	1	6	E-diary		None		
07JUL2020	1	7	E-diary		None						
07JUL2020	1	7	Unscheduled clinical assessment		None						

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
				01JUL2020		1	E-diary	Swelling	None		
				02JUL2020		2	E-diary		None		
				03JUL2020		3	E-diary		None		
				04JUL2020		4	E-diary		None		
				05JUL2020		5	E-diary		None		
				06JUL2020		6	E-diary		None		
				07JUL2020		7	E-diary		None		
				07JUL2020		7	Unscheduled clinical assessment		None		
				01JUL2020		1	E-diary	Pain at the injection site	None		
				02JUL2020		2	E-diary		None		
				03JUL2020		3	E-diary		None		
				04JUL2020		4	E-diary		None		
				05JUL2020		5	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
				06JUL2020		6	E-diary		None		
				07JUL2020		7	E-diary		None		
				07JUL2020		7	Unscheduled clinical assessment		None		
				01JUL2020		1	E-diary	Fever (°C)	None/36.7		
				02JUL2020		2	E-diary		None/36.8		
				03JUL2020		3	E-diary		None/36.7		
				04JUL2020		4	E-diary		None/36.8		
				05JUL2020		5	E-diary		None/36.4		
				06JUL2020		6	E-diary		None/36.8		
				07JUL2020		7	E-diary		None/37.2		
				07JUL2020		7	Unscheduled clinical assessment		None/36.2		
				01JUL2020		1	E-diary	Fatigue	Moderate		
				02JUL2020		2	E-diary		Moderate		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				03JUL2020		3	E-diary		Moderate		
				04JUL2020		4	E-diary		Moderate		
				05JUL2020		5	E-diary		Moderate		
				06JUL2020		6	E-diary		Moderate	06JUL2020	6
				07JUL2020		7	E-diary		None		
				07JUL2020		7	Unscheduled clinical assessment		None		
				01JUL2020		1	E-diary	Headache	None		
				02JUL2020		2	E-diary		Moderate		
				03JUL2020		3	E-diary		Moderate		
				04JUL2020		4	E-diary		Moderate		
				05JUL2020		5	E-diary		Mild		
				06JUL2020		6	E-diary		Moderate		
				07JUL2020		7	E-diary		Mild		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				07JUL2020		7	Unscheduled clinical assessment		None	11JUL2020	10
				01JUL2020		1	E-diary	Chills	None		
				02JUL2020		2	E-diary		None		
				03JUL2020		3	E-diary		None		
				04JUL2020		4	E-diary		None		
				05JUL2020		5	E-diary		None		
				06JUL2020		6	E-diary		None		
				07JUL2020		7	E-diary		None		
				07JUL2020		7	Unscheduled clinical assessment		None		
				01JUL2020		1	E-diary	Vomiting	None		
				02JUL2020		2	E-diary		None		
				03JUL2020		3	E-diary		None		
				04JUL2020		4	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
				05JUL2020		5	E-diary		None		
				06JUL2020		6	E-diary		None		
				07JUL2020		7	E-diary		None		
				07JUL2020		7	Unscheduled clinical assessment		None		
				01JUL2020		1	E-diary	Diarrhea	None		
				02JUL2020		2	E-diary		None		
				03JUL2020		3	E-diary		None		
				04JUL2020		4	E-diary		None		
				05JUL2020		5	E-diary		None		
				06JUL2020		6	E-diary		None		
				07JUL2020		7	E-diary		Mild		
				07JUL2020		7	Unscheduled clinical assessment		None	08JUL2020	2

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				01JUL2020	1		E-diary	New or worsened muscle pain	None		
				02JUL2020	2		E-diary		Moderate		
				03JUL2020	3		E-diary		Severe		
				04JUL2020	4		E-diary		None		
				05JUL2020	5		E-diary		Moderate		
				06JUL2020	6		E-diary		Moderate		
				07JUL2020	7		E-diary		Moderate		
				07JUL2020	7		Unscheduled clinical assessment		Severe	08JUL2020	7
				01JUL2020	1		E-diary	New or worsened joint pain	None		
				02JUL2020	2		E-diary		None		
				03JUL2020	3		E-diary		None		
				04JUL2020	4		E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
 Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
				05JUL2020		5	E-diary		None		
				06JUL2020		6	E-diary		Moderate	06JUL2020	1
				07JUL2020		7	E-diary		None		
				07JUL2020		7	Unscheduled clinical assessment		None		
				01JUL2020		1	E-diary	Use of antipyretic or pain medication	No		
				02JUL2020		2	E-diary		No		
				03JUL2020		3	E-diary		No		
				04JUL2020		4	E-diary		No		
				05JUL2020		5	E-diary		No		
				06JUL2020		6	E-diary		No		
				07JUL2020		7	E-diary		Yes	07JUL2020	1
				22JUL2020	2	1	E-diary	Redness	None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary ^b	Stop Date ^c	Dur (Days) ^d
				23JUL2020		2	E-diary		None		
				24JUL2020		3	E-diary		None		
				25JUL2020		4	E-diary		None		
				26JUL2020		5	E-diary		None		
				27JUL2020		6	E-diary		None		
				28JUL2020		7	E-diary		None		
				22JUL2020		1	E-diary	Swelling	None		
				23JUL2020		2	E-diary		None		
				24JUL2020		3	E-diary		None		
				25JUL2020		4	E-diary		None		
				26JUL2020		5	E-diary		None		
				27JUL2020		6	E-diary		None		
				28JUL2020		7	E-diary		None		
				22JUL2020		1	E-diary	Pain at the injection site	Mild	22JUL2020	1
				23JUL2020		2	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary ^b	Stop Date ^c	Dur (Days) ^d
				24JUL2020		3	E-diary		None		
				25JUL2020		4	E-diary		None		
				26JUL2020		5	E-diary		None		
				27JUL2020		6	E-diary		None		
				28JUL2020		7	E-diary		None		
				22JUL2020		1	E-diary	Fever (°C)	None/36.8		
				23JUL2020		2	E-diary		None/36.8		
				24JUL2020		3	E-diary		None/36.6		
				25JUL2020		4	E-diary		None/36.9		
				26JUL2020		5	E-diary		None/36.7		
				27JUL2020		6	E-diary		None/36.6		
				28JUL2020		7	E-diary		None/36.9		
				22JUL2020		1	E-diary	Fatigue	None		
				23JUL2020		2	E-diary		None		
				24JUL2020		3	E-diary		Moderate		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary ^b	Stop Date ^c	Dur (Days) ^d
				25JUL2020		4	E-diary		Moderate		
				26JUL2020		5	E-diary		Moderate		
				27JUL2020		6	E-diary		Moderate		
				28JUL2020		7	E-diary		Mild	30JUL2020	7
				22JUL2020		1	E-diary	Headache	None		
				23JUL2020		2	E-diary		None		
				24JUL2020		3	E-diary		Mild		
				25JUL2020		4	E-diary		Moderate		
				26JUL2020		5	E-diary		Moderate		
				27JUL2020		6	E-diary		Moderate		
				28JUL2020		7	E-diary		Mild	02AUG2020	10
				22JUL2020		1	E-diary	Chills	None		
				23JUL2020		2	E-diary		None		
				24JUL2020		3	E-diary		None		
				25JUL2020		4	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				26JUL2020		5	E-diary		None		
				27JUL2020		6	E-diary		None		
				28JUL2020		7	E-diary		None		
				22JUL2020		1	E-diary	Vomiting	None		
				23JUL2020		2	E-diary		None		
				24JUL2020		3	E-diary		None		
				25JUL2020		4	E-diary		None		
				26JUL2020		5	E-diary		None		
				27JUL2020		6	E-diary		None		
				28JUL2020		7	E-diary		None		
				22JUL2020		1	E-diary	Diarrhea	None		
				23JUL2020		2	E-diary		None		
				24JUL2020		3	E-diary		None		
				25JUL2020		4	E-diary		None		
				26JUL2020		5	E-diary		None		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
				27JUL2020		6	E-diary		None		
				28JUL2020		7	E-diary		None		
				22JUL2020		1	E-diary	New or worsened muscle pain	None		
				23JUL2020		2	E-diary		None		
				24JUL2020		3	E-diary		None		
				25JUL2020		4	E-diary		Moderate		
				26JUL2020		5	E-diary		None		
				27JUL2020		6	E-diary		Moderate	27JUL2020	3
				28JUL2020		7	E-diary		None		
				22JUL2020		1	E-diary	New or worsened joint pain	None		
				23JUL2020		2	E-diary		None		
				24JUL2020		3	E-diary		None		
				25JUL2020		4	E-diary		Moderate		

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day ^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement	Stop Date ^c	Dur (Days) ^d
									(caliper units) E-Diary ^b		
				26JUL2020		5	E-diary		None		
				27JUL2020		6	E-diary		Moderate		
				28JUL2020		7	E-diary		Moderate	30JUL2020	6
				22JUL2020		1	E-diary	Use of antipyretic or pain medication	No		
				23JUL2020		2	E-diary		No		
				24JUL2020		3	E-diary		No		
				25JUL2020		4	E-diary		Yes		
				26JUL2020		5	E-diary		Yes		
				27JUL2020		6	E-diary		Yes	27JUL2020	3
				28JUL2020		7	E-diary		No		

Note: Temperature measurement is included at an unscheduled visit only when pain at the injection site, redness, or swelling assessment is also collected.

Note: The maximum measurable size in the electronic diary (e-diary) is 21 caliper units. Redness and swelling exceeding 21 caliper units cannot be precisely recorded and are therefore reported as >21. For all measurements, 1 caliper unit = 0.5 centimeters.

a. Relative Day (Rel Day) = date of local reaction or systemic event - date of last vaccination + 1.

b. Severity for redness and swelling: mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only). Severity for pain at the injection site: mild: does not interfere with activity; moderate:

**16.2.7.8.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Each Dose – Phase 1, 2 Doses, 21 Days Apart**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
<p>interferes with activity; severe: prevents daily activity. Grade 4: emergency room visit or hospitalization for severe pain at the injection site.</p> <p>c. If the reaction or event lasted 7 days or less, the stop date is the last day the reaction or event was recorded in the electronic diary (e-diary). If the reaction or event continued beyond Day 7, the stop date was collected on the subject's case report form.</p> <p>d. Duration (days) was calculated as the difference from the start of the first reported reaction or event to resolution of the last reported reaction or event, inclusive.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 29AUG2020 (02:28) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adce 1007 p1</p>											

**16.2.7.8.1.1 Listing of E-Diary Reactions or Events and Corresponding Assessments at
Unscheduled Visits Within 7 Days After Dose 1 – Phase 1 – BNT162b1 (100 µg)**

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Administered)	Subject	Assessment Date	Dose No.	Rel Day^a	Assessment Type	Local Reaction or Systemic Event	Severity/ Measurement (caliper units) E-Diary^b	Stop Date^c	Dur (Days)^d
No subject meets the reporting criteria.											
<p>Note: Temperature measurement is included at an unscheduled visit only when pain at the injection site, redness, or swelling assessment is also collected. Note: The maximum measurable size in the electronic diary (e-diary) is 21 caliper units. Redness and swelling exceeding 21 caliper units cannot be precisely recorded and are therefore reported as >21. For all measurements, 1 caliper unit = 0.5 centimeters.</p> <p>a. Relative Day (Rel Day) = date of local reaction or systemic event - date of last vaccination + 1. b. Severity for redness and swelling: mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only). Severity for pain at the injection site: mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity. Grade 4: emergency room visit or hospitalization for severe pain at the injection site. c. If the reaction or event lasted 7 days or less, the stop date is the last day the reaction or event was recorded in the electronic diary (e-diary). If the reaction or event continued beyond Day 7, the stop date was collected on the subject's case report form. d. Duration (days) was calculated as the difference from the start of the first reported reaction or event to resolution of the last reported reaction or event, inclusive.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:29) Source Data: adfacevd Table Generation: 18SEP2020 (12:27) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001 IA P1 100/adce 1007 100 p1</p>											