

### 16.2.1.1 Listing of Subjects Withdrawn From the Study – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
No subject meets the reporting criteria.									
<p>a. Relative Day (Rel Day) = date of withdrawal - date of last vaccination + 1. For a withdrawal that occurred before the date of the first study vaccination, +1 was not added to compute relative day.</p> <p>b. MedDRA (v23.0) coding dictionary applied.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adds Table Generation: 29AUG2020 (08:38)            (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adds 1001 p1</p>									

### 16.2.1.1.1 Listing of Subjects Withdrawn From the Study Before Dose 2 – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
No subject meets the reporting criteria.									
<p>a. Relative Day (Rel Day) = date of withdrawal - date of last vaccination + 1. For a withdrawal that occurred before the date of the first study vaccination, +1 was not added to compute relative day.</p> <p>b. MedDRA (v23.0) coding dictionary applied.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adds Table Generation: 19SEP2020 (10:19)            (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001 IA P1 100/adds 1001 100 p1</p>									

### 16.2.1.2 Listing of Subjects Withdrawn From the Study – Phase 2

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
18-55	C4591001 1079 10791004	1	23	20AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ADENOCARCINOMA GASTRIC
		1	30	27AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT

a. Relative Day (Rel Day) = date of withdrawal - date of last vaccination + 1. For a withdrawal that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. MedDRA (v23.0) coding dictionary applied.

PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (14:11) Source Data: adds Table Generation: 09SEP2020 (23:17)  
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2\_unblinded/C4591001\_IA\_P2/adds\_1001\_withdraw\_p2

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
16-55	C4591001 1001 10011125	1	37	09SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrew consent and decided not to continue in study.
		1	37	09SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1003 10031140			04AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Randomized in error.
				04AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Randomized in error.
	C4591001 1005 10051308	1	1	19OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	busy work schedule
		1	1	19OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	busy work schedule
	C4591001 1005 10051341	1	2	22OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject tested COVID positive between visits 1 and 2
				28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject decided to withdraw consent after randomized in IVRS but before given vaccine
	C4591001 1007 10071179	2	29	01OCT2020	VACCINATION	LOST TO FOLLOW-UP	phone attempt 01oct2020, 02oct2020, 05oct2020; certified letter 05oct2020
		2	29	01OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	phone attempt 01oct2020, 02oct2020, 05oct2020; certified letter 05oct2020
C4591001 1007 10071407	1	15	05NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion # 5; Subject has diagnosis of COVID-19 with positive PCR and symptoms	

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1008 10081529	1	5	29SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject tested positive for COVID19
	C4591001 1008 10081721	1	13	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject tested positive for COVID 19
	C4591001 1009 10091211	1	19	03NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject tested positive for COVID-19
	C4591001 1009 10091257	1	10	05NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	positive for COVID-19
	C4591001 1012 10121001	1	26	28AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject refused second vaccination; will continue in study for follow-up.
	C4591001 1012 10121103	2	2	23SEP2020	VACCINATION	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT
		2	2	23SEP2020	FOLLOW-UP	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT
	C4591001 1012 10121163	1	16	24SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE DERMATITIS
		1	39	17OCT2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1013 10131017			30JUL2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT FROM STUDY.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1013 10131046	2	70	27OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject is lost to follow up. certified letter sent and emailed 10-02-2020
		2	70	27OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT IS LOST TO FOLLOW UP.
	C4591001 1013 10131048	2	28	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	New job
		2	28	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	New Job
	C4591001 1013 10131054	2	7	30AUG2020	VACCINATION	LOST TO FOLLOW-UP	Attempted contact
		2	7	30AUG2020	FOLLOW-UP	LOST TO FOLLOW-UP	Contact attempted
	C4591001 1013 10131131	2	36	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	Certified letter sent
		2	36	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent
	C4591001 1013 10131138	1	23	02SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT FROM THE STUDY
		1	23	02SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT.
	C4591001 1013 10131216	1	46	02OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew from study
		1	46	02OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT DUE TO FAMILY SITUATION.
	C4591001 1013 10131332	2	56	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	UNKOWN

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		2	56	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	UNKNOWN
	C4591001 1013 10131426	1	1	03SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject has not returned for next visit. is now considered lost to follow up
		1	1	03SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject is lost to follow up.
	C4591001 1013 10131592	2	31	11NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent from study.
		2	31	11NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	MOVED OUT OF STATE NO LONGER WANTED TO PARTICIPATE.
	C4591001 1013 10131670†	1	4	11OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	SUBJECT TESTED POSITIVE FOR COVID-19
	C4591001 1013 10131740			15OCT2020	FOLLOW-UP	OTHER	randomized in error, needed to wait until course of antibiotics was done.
	C4591001 1013 10131746	1	22	09NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Currently taking corticosteroids
		1	22	09NOV2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Currently taking exclusionary medication
	C4591001 1015 10151030	2	64	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up after multiple contact attempts and receipt of certified letter
		2	64	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up after multiple contact attempts and receipt of certified letter
	C4591001 1015 10151134	1	72	06NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/VERTIGO

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1015 10151199	1	24	01OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject decided not to continue with study.
		1	24	01OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
	C4591001 1016 10161047	1	24	27AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject stated at visit 2, had positive COVID test
	C4591001 1016 10161087	1	22	31AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE SWELLING
	C4591001 1016 10161126	1	39	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject declined further study vaccines,subject will continue with rest of visits and procedures
	C4591001 1016 10161341	1	10	31OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject with a positive covid-19 test
	C4591001 1018 10181025	1	45	16SEP2020	VACCINATION	LOST TO FOLLOW-UP	Follow-up attempts made on 21-Aug, 1-Sep, and 4-Sep with no response.
		1	45	16SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Follow-up attempts made on 21-Aug, 1-Sep, and 4-Sep. Certified letter sent 9-Sep-2020.
	C4591001 1018 10181036	1	45	16SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject missed V2 and did not respond to 3 Follow-up attempts.
		1	45	16SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	no response to multiple follow up calls and contact attempts
	C4591001 1018 10181054	1	39	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	patient returned to home country, did not respond to outreach, certified letter sent



## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	39	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject returned to home country, according to call to emergency contact
	C4591001 1018 10181142	1	33	14SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject did not arrive at scheduled second visit and texted no longer wants to participate in study.
		1	33	14SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not arrive at scheduled second visit and texted no longer wants to participate in study.
	C4591001 1018 10181266	1	41	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdraw from study due to work schedule
		1	41	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdraw from study due to work schedule
	C4591001 1019 10191098	1	18	11SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Pt discontinued due to positive covid test. Will f/u with pt
	C4591001 1019 10191166	1	22	25SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
		1	22	25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
	C4591001 1027 10271105	1	15	11SEP2020	VACCINATION	ADVERSE EVENT	Subject has discontinued Study Drug. Subject has agreed to continue with follow-up visits./ALLERGY TO VACCINE
	C4591001 1028 10281072	1	55	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	certified letter returned unclaimed 20oct2020
		1	55	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter came back unclaimed on 20Oct2020
	C4591001 1028 10281294	1	7	04NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	patient had positive covid test prior to V2

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1036 10361011	1	1	20AUG2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
		1	1	20AUG2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1036 10361032	2	48	03NOV2020	VACCINATION	LOST TO FOLLOW-UP	unreachable
		2	48	03NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	unreachable
	C4591001 1036 10361050			31AUG2020	FOLLOW-UP	OTHER	Subject randomized in error due to prohibitive drug.
	C4591001 1037 10371068	1	3	27AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	SUBJECT MET EXCL CRIT # 13
	C4591001 1037 10371077	1	66	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SPOKE WITH SUBJECT ON 30 OCT. DUE TO SCHEDULE, HE CAN NO LONGER CONTINUE WITH STUDY VISITS
		1	66	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SPOKE WITH SUBJECT ON 30 OCT. DUE TO SCHEDULE, HE CAN NO LONGER ATTEND VISITS
	C4591001 1037 10371078	1	44	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	SITE ATTEMPTED CONTACT ON 22 SEP 30 SEP AND CERTIFIED LETTER SENT 8 OCT NO RESPONSE
		1	44	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 8 OCT. PT DID NOT RESPOND
	C4591001 1039 10391021	1	24	17SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient tested positive for COVID-19.
	C4591001 1039 10391080	1	21	23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient withdrew consent. Patient will not be participating in follow-ups.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	21	23SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew from study and follow up.
	C4591001 1042 10421069	1	22	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		1	22	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1042 10421079	2	55	02NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow-up after unsuccessful attempts to contact
		2	55	02NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up after unsuccessful attempts to make contact.
	C4591001 1042 10421092	2	27	06OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject called the office in withdrew consent-they will not be returning to the site for future visi
		2	27	06OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew from study participation
	C4591001 1042 10421093	2	48	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up after unsuccessful attempts to make contact.
		2	48	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up after unsuccessful attempts to make contact.
	C4591001 1042 10421129	2	41	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up after unsuccessful attempts to make contact.
		2	41	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up after unsuccessful attempts to make contact.
	C4591001 1042 10421250	1	58	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
		1	58	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1042 10421251	1	58	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
		1	58	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1046 10461040	1	15	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject chose to discontinue due to personal reasons.
		1	15	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Decision
	C4591001 1046 10461049	2	31	09OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject Withdrew
		2	31	09OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject decision
	C4591001 1046 10461099	1	64	27OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject Decision
		1	64	27OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Decision
	C4591001 1046 10461140	1	22	19SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject Decision
		1	22	19SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Decision
	C4591001 1047 10471221	1	44	29OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent
		1	44	29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1047 10471314	1	32	12NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject is lost to follow up
	C4591001 1052 10521021	2	63	11NOV2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow up
		2	63	11NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001 1052 10521022	2	63	11NOV2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow up
		2	63	11NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001 1052 10521054	1	25	21SEP2020	VACCINATION	LOST TO FOLLOW-UP	n/a
		1	25	21SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001 1052 10521057	1	25	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent
		1	25	21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrawal by subject
	C4591001 1052 10521058	1	25	21SEP2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow up
		1	25	21SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001 1052 10521064	1	25	24SEP2020	VACCINATION	LOST TO FOLLOW-UP	n/a
		1	25	24SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost of follow up

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1052 10521080	1	28	29SEP2020	VACCINATION	LOST TO FOLLOW-UP	lost of follow up
		1	28	29SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost of follow up
	C4591001 1054 10541022	1	64	23OCT2020	VACCINATION	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
		1	64	23OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
	C4591001 1054 10541023	1	64	23OCT2020	VACCINATION	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
		1	64	23OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
	C4591001 1054 10541033	1	21	11SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Per sponsor, participant met EXC #5, and should not receive VAX2 but may remain in study.
	C4591001 1054 10541055	1	59	23OCT2020	VACCINATION	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
		1	59	23OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
	C4591001 1054 10541064	1	78	12NOV2020	VACCINATION	LOST TO FOLLOW-UP	> 3 attempts at contacting pt via telephone; certified letter sent
		1	78	12NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	> 3 attempts at contacting pt via telephone; certified letter sent
	C4591001 1054 10541138	1	23	02OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject doesn't want to continue in study.
		1	23	02OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject doesn't want to continue in study.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1054 10541150	1	22	05OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	No longer interested in study, and walked out of clinic w/o talking to Investigator.
		1	22	05OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt is no longer interested in study. Walked out of clinic w/o seeing the Investigator.
	C4591001 1055 10551145	1	48	14OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DYSPHAGIA
	C4591001 1056 10561027	1	35	25SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject couldn't be reached. Caregiver states he left the house and nobody knows where he is.
		1	35	25SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject couldn't be reached. Caregiver states he left the house and nobody knows where he is.
	C4591001 1056 10561129	1	24	25SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject states he doesn't want to continue in the study
		1	24	25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject states he doesn't want to continue in the study
	C4591001 1056 10561152	1	27	29SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT STATED HE DOES NOT WANT TO CONTINUE HIS PARTICIPATION IN THE STUDY.
		1	27	29SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT STATED HE DOES NOT WANT TO CONTINUE HIS PARTICIPATION IN THE STUDY.
	C4591001 1056 10561253	2	32	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT MOVED OUT OF STATE AND HE IS UNABLE TO CONTINUE PARTICIPATING IN THE STUDY.
		2	32	05NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT MOVED OUT OF STATE AND HE IS UNABLE TO CONTINUE PARTICIPATING IN THE STUDY.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1056 10561293	1	50	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
		1	50	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
	C4591001 1056 10561372	1	38	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
		1	38	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
	C4591001 1056 10561395	1	25	29OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT MOVED TO ANOTHER TOWN
		1	25	29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject moved out of town.
	C4591001 1057 10571031			18AUG2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	met delay criteria, reported by subject after subject was randomized, discontinued prior to vaccine
	C4591001 1057 10571211			18SEP2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	subject was randomized but failed to meet entry criteria, no vaccine was given
	C4591001 1057 10571212			18SEP2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	subject was randomized and then failed to meet criteria, no vaccine was administered
	C4591001 1057 10571215			18SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	refused further study procedures
	C4591001 1057 10571216	2	30	10NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	MOVED TO SAN FRANCISCO



### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		2	30	10NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	MOVED TO SAN FRANCISCO
	C4591001 1057 10571248	1	36	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject refused to return for Visit 2, withdrew consent, No adverse events reported
		1	36	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent from further study participation
	C4591001 1057 10571268			06OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	w/d consent
	C4591001 1066 10661335			14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent to participate
	C4591001 1071 10711095	1	61	24OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT IS LOST TO FOLLOW UP
		1	61	24OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT IS LOST TO FOLLOW UP
	C4591001 1071 10711162			11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	During discussing the diary, the subject withdrew consent and subject left.
				11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1071 10711211	1	32	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT TO 2ND INJECTION BUT WILL RETURN FOR FOLLOW UP VST
	C4591001 1072 10721051	1	12	06SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	diagnosis COVID-19 exclusion 5
	C4591001 1073 10731038	1	37	10SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject was Discontinue

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	37	10SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Discontinue
	C4591001 1079 10791004	1	23	20AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ADENOCARCINOMA GASTRIC
		1	30	27AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1079 10791040	2	45	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject has not returned calls, emails or letters
		2	45	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is lost to follow up
	C4591001 1079 10791130	1	1	17AUG2020	VACCINATION	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT	MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT
	C4591001 1079 10791253	1	67	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	patient unresponsive
	C4591001 1081 10811071	1	48	05OCT2020	VACCINATION	LOST TO FOLLOW-UP	lack of follow-up, does not return calls & had multiple no show appointments
		1	48	05OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to reach subj, multiple no-show appts. This was the last scheduled visit that was a no-show.
	C4591001 1081 10811105			26AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1081 10811194	2	34	01NOV2020	FOLLOW-UP	DEATH	DEATH
	C4591001 1082 10821013			03AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject was randomized but left site prior to receiving vaccination.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1082 10821077	1	22	28AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	scheduling conflicts. live out of state.
		1	22	28AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1082 10821078	1	22	28AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	scheduling conflicts. live out of state.
		1	22	28AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1082 10821145	2	30	23OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent due to occupation
		2	30	23OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent due to occupation
	C4591001 1083 10831029	1	20	23AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ATRIAL FIBRILLATION
	C4591001 1083 10831060	1	9	14AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DIVERTICULAR PERFORATION
	C4591001 1083 10831141	1	34	23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject no longers wants to participate in the study subject was offered safety F/U Sub Declined
		1	34	23SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject decision Subject no longers wants to participate in the study subject was offered safety F/U
	C4591001 1083 10831187	2	28	22OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT MOVE OUT OF STATE
		2	28	22OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	22OCT2020 subject was contacted for V3 Appointment reminder 23OCT2020 and verbally withdrew consent

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1083 10831219	2	37	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject was contacted to reschedule Visit 3 and he withdrew consent
		2	37	05NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	05NOV2020 After multiple attempts to contact subj to reschedule V3 subj returned call and WC
	C4591001 1084 10841035	1	22	24AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject does not want to do study anymore; now engaged and wants to start a family
		1	22	24AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent because subject wants to start a family
	C4591001 1084 10841057	1	35	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject never answered phone calls; certified letter sent
		1	35	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject never answered phone calls; certified letter sent
	C4591001 1084 10841119	2	38	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	certified letter sent
		2	38	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject LTFU; certified letter sent
	C4591001 1084 10841272	1	32	22SEP2020	VACCINATION	LOST TO FOLLOW-UP	LTFU
		1	32	22SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	LTFU
	C4591001 1085 10851286	1	34	12OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Positive COVID-19 test result prior to vaccination 2 as such subject meets exclusion criteria.
		1	58	05NOV2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Positive Covid test prior to vaccine 2
	C4591001 1087 10871085	2	13	20SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Pt moved to another State for job. Closest Site 1+ hr away from pt's new location. Withdrew consent.

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		2	13	20SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt moved to another State for job. Closest Site 1+ hr away from pt's new location. Withdrew consent.
	C4591001 1087 10871089	1	19	04SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria #5
	C4591001 1087 10871209	1	7	31AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject has met exclusion #5
		1	38	01OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject chose to withdraw from study because felt no longer necessary due to positive COVID dx.
	C4591001 1087 10871336	1	61	02NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
		1	61	02NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1087 10871354	1	10	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject does not feel comfortable continuing in the study. Withdrawal of participation and consent.
		1	10	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject does not feel comfortable continuing in study. Withdrawal of participation & consent.
	C4591001 1087 10871356	1	54	31OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up.
		1	54	31OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up.
	C4591001 1087 10871557	1	23	05NOV2020	VACCINATION	PREGNANCY	PREGNANCY
	C4591001 1089 10891076	1	22	27AUG2020	VACCINATION	LOST TO FOLLOW-UP	8/25-# out of service, sent email 8/27-no response, sent certified letter
		1	22	27AUG2020	FOLLOW-UP	LOST TO FOLLOW-UP	number invalid and sent certified letter. no response

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1089 10891158	1	44	02OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	site was notified that subject has been incarcerated and will not be able to complete study visit
		1	44	02OCT2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	site was notified that subject has been incarcerated and will not be able to complete study visit
	C4591001 1089 10891346			22SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent prior to receiving vaccine
	C4591001 1089 10891351			25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent, and left office prior to vaccination
	C4591001 1090 10901047	2	45	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	Pt was not reachable the last 2 weeks. HE is in prison per his sister. Pt will be discontinued.
		2	45	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	pt in prison
	C4591001 1090 10901068	1	29	02SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	pt is not willing to come to any m visits
		1	29	02SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject no longer interested in study
	C4591001 1090 10901379	1	54	02NOV2020	VACCINATION	LOST TO FOLLOW-UP	pt never contacted us to reschedule V2
		1	54	02NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to contact
	C4591001 1090 10901507	1	20	04NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/URTICARIA
	C4591001 1091 10911039	1	50	22SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent to future visits

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	50	22SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent to further visits
	C4591001 1091 10911077	1	22	27AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient agrees to stay in the trial for follow up but denied second vaccination.
	C4591001 1091 10911083	1	23	28AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Did not want to come to scheduled visits
		1	23	28AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject no longer wanted to come to study appointments
	C4591001 1091 10911352	1	23	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject was a NCNS for his V2 today. Stated over the phone he would like to withdraw consent
		1	23	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject was a NCNS for his V2. Stated over the phone he would like to withdraw consent
	C4591001 1091 10911387	1	5	09NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	NO LONGER MEETS ELIGIBILITY CRITERIA
	C4591001 1092 10921080	1	22	16SEP2020	VACCINATION	OTHER	Incarcerated 09Sep2020
		1	22	16SEP2020	FOLLOW-UP	OTHER	Incarcerated
	C4591001 1092 10921082	2	35	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	unable to make contact with subject
		2	35	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is Lost to follow up
	C4591001 1092 10921128			01SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt withdrew consent due to anxiety of having blood drawn

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1092 10921130	2	21	12OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	confirmed covid illness
	C4591001 1093 10931055			31AUG2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	UNABLE TO OBTAIN BLOOD FROM SUBJECT.
	C4591001 1093 10931058	1	25	18SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/EXPOSURE DURING PREGNANCY
	C4591001 1093 10931065	1	81	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AND WAS UNABLE TO BE CONTACTED MULTIPLE TIMES.
		1	81	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AND WAS UNABLE TO BE CONTACTED MULTIPLE TIMES.
	C4591001 1093 10931094	1	76	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AFTER MULTIPLE ATTEMPTS TO CONTACT THEM.
		1	76	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AFTER MULTIPLE ATTEMPTS TO CONTACT THEM.
	C4591001 1095 10951056	1	35	08SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Participant is no longer able to participate
		1	37	10SEP2020	FOLLOW-UP	OTHER	Participant not able to continue in study at this time. Participant did not withdraw consent
	C4591001 1095 10951110	1	71	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	completed Vac 1, but declined vac 2 but will participate in all other study procedures. approved MD
	C4591001 1095 10951141	1	22	16SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT



### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	22	16SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/DIABETIC FOOT
	C4591001 1095 10951168	1	48	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject will not receive vaccination however will participate in all other study procedures
	C4591001 1095 10951173	1	8	05SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ACUTE MYOCARDIAL INFARCTION
	C4591001 1096 10961031	1	22	04SEP2020	VACCINATION	PREGNANCY	PREGNANCY
	C4591001 1096 10961081	1	54	12OCT2020	VACCINATION	LOST TO FOLLOW-UP	LTFU, unresponsive to contact attempts
		1	54	12OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	site unable to contact subject after multiple attempts and certified letter sent
	C4591001 1096 10961141	1	22	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	per protocol
	C4591001 1096 10961276	1	21	25SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	due to moving out of town unexpectedly
		1	21	25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	due to moving out of town unexpectedly
	C4591001 1096 10961321	1	22	03OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject met exclusion #1 on visit 2 (suicidal ideation) so no vaccine was administered
	C4591001 1096 10961388	1	21	29OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject was diagnosed with COVID between vaccination one and vaccination two

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1098 10981001	1	31	17SEP2020	VACCINATION	LOST TO FOLLOW-UP	Lost to followup
		1	31	17SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter was sent. Site is unable to contact the subject. Thanks.
	C4591001 1098 10981029	1	22	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject wanted to be discontinued from the study for unknown reasons.
		1	22	11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject inform, it is due to wellbeing
	C4591001 1098 10981200	1	46	05NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject called multiple times and certified letter was sent. No response from subject
		1	46	05NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject called multiple times and certified letter was sent. No response from subject.
	C4591001 1098 10981219	1	43	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdraw by subject due to no longer wanting to take part in the study.
		1	43	05NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdraw by subject due to no longer wanting to take part in the study.
	C4591001 1101 11011024	1	21	29SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	the subject was diagnoses with COVID between vaccination one and vaccination two
	C4591001 1107 11071074	2	74	12NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT ON 12NOV2020
	C4591001 1109 11091030	2	37	23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT CALLED TO WITHDRAW FROM TRIAL DUE TO TRANSPORTATION ISSUES AS WELL AS BEING TO BUSY.

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		2	37	23SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT CALLED TO WITHDRAW FROM TRIAL DUE TO TRANSPORTATION ISSUES AS WELL AS BEING TOO BUSY.
	C4591001 1109 11091059	1	40	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RETURNED PHONE CALLS OR RESPOND TO CERTIFIED LETTER.
		1	40	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RETURNED PHONE CALLS OR RESPOND TO CERTIFIED LETTER.
	C4591001 1109 11091068	1	40	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RETURNED NUMEROUS CALLS OR CERTIFIED LETTER SENT TO HIM.
		1	40	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO CALLS OR CERTIFIED LETTER.
	C4591001 1109 11091127	1	37	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT TO HER
		1	37	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO CALLS OR CERTIFIED LETTER SENT TO HER.
	C4591001 1109 11091148	2	33	26SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT CALLED AND WITHDREW CONSENT
		2	33	26SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT CALLED AND WITHDREW CONSENT
	C4591001 1109 11091234	1	25	08SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	WORK HAD GOTTEN TOO BUSY WITH OPENING BACK UP AND SHE WAS UNABLE TO CONTINUE HER PARTICIPATION.
		1	25	08SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	WORK HAD GOTTEN TOO BUSY WITH OPENING BACK UP AND SHE WAS UNABLE TO CONTINUE HER PARTICIPATION.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1109 11091335	1	43	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT TO HER
		1	43	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT TO HER
	C4591001 1109 11091349			28AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error.
	C4591001 1109 11091419	2	40	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not respond to multiple phone calls or certified letter.
		2	40	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not respond to multiple phone calls or certified letter.
	C4591001 1109 11091478	1	29	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
		1	29	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT
	C4591001 1109 11091515	1	30	14OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject never returned for visit, responded to call or certified letter sent.
		1	30	14OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject never returned for visit, responded to call or certified letter sent.
	C4591001 1109 11091556	1	9	12OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1110 11101006	1	53	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject meets exclusion criteria #5

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1110 11101010	2	63	22OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not comply with inclusion criteria #2.
		2	63	22OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not comply with inclusion criteria #2.
	C4591001 1110 11101038	1	35	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject was contact over the phone 3 times and a certified letter was sent. Subject never reply.
		1	35	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow is status, subject has been withdrawn from trial.
	C4591001 1110 11101039	1	35	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject failed to contact site after many calls and certified letter.
		1	35	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not respond to many phones calls from site and did not respond to certified letter fromi
	C4591001 1110 11101069	1	59	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject was called more the 3 times,was texted 2 times,email/certified letter were sent
		1	59	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	we did more than 3 attempts via phone, 1 text message, 4 emails and a certified letter.
	C4591001 1110 11101085	1	58	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject was tried to contact by phone, text, email and certified letter several times.
		1	58	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	we did 4 phone call attempts, 1 text message, 1 email and a certified letter.
	C4591001 1110 11101110	1	22	08SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		1	22	08SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1110 11101141	2	56	12NOV2020	VACCINATION	LOST TO FOLLOW-UP	4 attempts via phone call, 1 text message, 1 email and 1 certified letter.
		2	56	12NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	4 attempts via phone call, 1 text message, 1 email and 1 certified letter.
	C4591001 1110 11101154	1	21	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject was contacted over the phone because she missed visit 2 and subject withdraw consent.
		1	21	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent verbally over the phone.
	C4591001 1110 11101155	1	21	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject was contacted over the phone because she missed visit 2 and subject withdraw consent.
		1	21	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject verbally withdrew consent.
	C4591001 1110 11101229	1	21	30SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject meets exclusion criterion #5
	C4591001 1110 11101247	1	22	06OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject WICF because he is unable to continue with the visit due to work.
		1	22	06OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject WICF because he is unable to continue with the visit due to work.
	C4591001 1110 11101250	1	22	06OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject did not provide a reason to be discontinued from the study.
		1	22	06OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not provide a reason to be discontinued from the study.
	C4591001 1110 11101333	1	35	05NOV2020	VACCINATION	LOST TO FOLLOW-UP	we attempt 3 phone calls, 1 text message and 1 certified letter.

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	35	05NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	we attempt 3 phone calls, 1 text message and 1 certified letter.
	C4591001 1110 11101342	1	31	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject sent and email, he state he will like to withdraw from the study due to a private reason.
		1	31	05NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject sent and email, he state he will like to withdraw from the study due to a private reason.
	C4591001 1111 11111099	1	71	20OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject refused second vaccination but will continue with follow-up procedures
	C4591001 1112 11121054	2	43	07OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent due to work schedule
		2	43	07OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew due to busy work schedule
	C4591001 1112 11121058	1	22	25AUG2020	VACCINATION	OTHER	(b) (6)
		1	22	25AUG2020	FOLLOW-UP	OTHER	(b) (6)
	C4591001 1112 11121192	1	34	30SEP2020	VACCINATION	LOST TO FOLLOW-UP	unable to reach subject for missed appts
		1	34	30SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact subject for Vs 2
	C4591001 1112 11121229			04SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject left clinic after randomization and prior to vaccination
	C4591001 1112 11121270†	1	1	08OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	unstable viral load and Hepatitis B

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1114 11141029	2	45	29OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject no show to apt and no response from certified letter.
		2	45	29OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject no show to apt and no response from certified letter.
	C4591001 1114 11141037	1	54	09OCT2020	VACCINATION	LOST TO FOLLOW-UP	no show to visit 2,two times.subject no responsive to calls and voicemails and subjects emerg.contac
		1	54	09OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	no show to visit 2,two times.subject no responsive to calls and voicemails and subjects emerg.contac
	C4591001 1116 11161015			26AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent. Left site prior to IP administration.
	C4591001 1116 11161143	1	68	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	Contact attempts 29SEP 30SEP 2OCT 13OCT 6NOV 9NOV
		1	68	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Contact attempts 29SEP 30SEP 2OCT 13OCT 6NOV 9NOV
	C4591001 1116 11161172	1	67	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	Contact attempts 2OCT 5OCT 7OCT 9OCT 13OCT 23OCT 9NOV
		1	67	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Contact attempts 2OCT 5OCT 7OCT 9OCT 13OCT 23OCT 9NOV
	C4591001 1116 11161292	1	52	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	Contact attempts 16OCT 22OCT 23OCT 3NOV 4NOV 9NOV 10NOV
		1	52	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Contact attempts 16OCT 22OCT 23OCT 3NOV 4NOV 9NOV 10NOV
	C4591001 1117 11171186	1	21	26OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	SAE EVENT, INVESTIGATOR DETERMINED SUBJECT NO LONGER MEETS CRITERIA FOR INCLUSION



### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1120 11201013	1	20	18AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject states he no longer wants to be in study
		1	20	18AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject states he no longer wants to be in study
	C4591001 1120 11201038			04AUG2020	SCREENING	SCREEN FAILURE	SCREEN FAILURE
	C4591001 1120 11201083	2	71	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	certified letter sent and moved to lost to follow up
		2	71	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up
	C4591001 1120 11201085	1	79	23OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject would not come in office for visit
		1	79	23OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject never showed to appointment.
	C4591001 1120 11201104	1	50	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject states no longer wishes to be in study about to have weight lost surgery
		1	50	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wished to be in study subject is about to have weight lost surgery
	C4591001 1120 11201249	1	50	09OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT IS STILL BEING FOLLOWED JUST REFUSED VAX 2
		1	50	09OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject still being followed. refused vax 2
	C4591001 1120 11201252			09SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was randomized, but had to leave for work. Subject never return for next appointment

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1121 11211009	2	40	22OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew due to busy schedule.
		2	40	22OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent due to busy schedule. Does not want to be FU
	C4591001 1121 11211025	1	22	16SEP2020	VACCINATION	OTHER	Participants significant other notified the site, participant is in jail for the foreseeable future
		1	22	16SEP2020	FOLLOW-UP	OTHER	Subject incarcerated. Subject to be dropped from the study.
	C4591001 1122 11221006			03SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error
	C4591001 1122 11221026			11SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/PRESYNCOPE
				11SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/VOMITING
	C4591001 1123 11231027			04AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent after randomization prior to vaccination.
	C4591001 1123 11231051	2	43	08OCT2020	VACCINATION	OTHER	moved to hawaii
		2	43	08OCT2020	FOLLOW-UP	OTHER	Moved to Hawaii
	C4591001 1123 11231144	1	42	30SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criteria #5.
	C4591001 1123 11231154	1	73	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	no response from subject after certified letter
		1	73	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	no response from subject after certified letter

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1123 11231168	1	72	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	Pt is LTF
		1	72	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt is LTF
	C4591001 1123 11231290	1	29	21OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent.
		1	29	21OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent.
	C4591001 1123 11231301			24SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	subject randomized in error
	C4591001 1123 11231313	1	13	06OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exc. criterion 5 COVID-19 positive
	C4591001 1123 11231386	1	22	09NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	exclusion no. 5 positive covid test
	C4591001 1124 11241049	1	26	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject not responding to any phone calls, certified letter sent
		1	26	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject not responding to any phone calls, certified letter sent
	C4591001 1124 11241084	1	10	02SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or Microbiological COVID 19 Diagnosis
		1	18	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject not interested in participating any longer
	C4591001 1125 11251019	1	48	29SEP2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	48	29SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	post to follow
	C4591001 1125 11251022	2	57	28OCT2020	VACCINATION	LOST TO FOLLOW-UP	patient is a lost to follow
		2	57	28OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient was a lost to follow
	C4591001 1125 11251148	1	43	14OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject tested positive for Covid-19
	C4591001 1125 11251159	1	1	03SEP2020	VACCINATION	LOST TO FOLLOW-UP	attempted to contact patient and sent certified letter with no response back
		1	1	03SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient is a lost to follow
	C4591001 1125 11251160	1	33	05OCT2020	VACCINATION	LOST TO FOLLOW-UP	Patient is a lost to follow
		1	33	05OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow
	C4591001 1126 11261074			25AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	During enrollment, after consent signed, inc/exc criteria reviewed, serology/nasal swab completed
	C4591001 1127 11271022	1	50	17SEP2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1127 11271099	1	22	09SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject tested positive and symptoms for COVID
	C4591001 1128 11281055	2	65	29OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject contact attempted several times, certified letter sent, no response
		2	65	29OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	after several attempts and certified letter, subject has not responded

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1128 11281086	2	43	13OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject wishes to discontinue from study
		2	43	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject wished to discontinue study
	C4591001 1128 11281146	1	64	21OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject is lost to follow up
		1	64	21OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER SEVERAL ATTEMPTS TO CONTACT, CERTIFIED LETTER SENT 16SEP2020
	C4591001 1128 11281159	2	49	29OCT2020	VACCINATION	LOST TO FOLLOW-UP	after several attempts and certified letter sent, subject is lost to follow up
		2	49	29OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	after several attempts and certified letter sent, subject is lost to follow up
	C4591001 1128 11281164	2	61	10NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT, GOT A NEW JOB AND CAN'T RETURN FOR VISITS
		2	61	10NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT, GOT A NEW JOB AND CAN'T RETURN FOR VISITS
	C4591001 1128 11281279	2	48	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	AFTER SEVERAL ATTEMPTS TO REACH SUBJECT, CERTIFIED LETTER WAS SENT WITH NO RESPONSE
		2	48	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	AFTER SEVERAL ATTEMPTS TO REACH SUBJECT, CERTIFIED LETTER WAS SENT WITH NO RESPONSE
	C4591001 1128 11281368	1	46	31OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT DID NOT RETURN TO CLINIC FOR V2. CERTIFIED LETTER SENT
		1	46	31OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT DID NOT RETURN TO CLINIC FOR V2. CERTIFIED LETTER SENT

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1129 11291048			04AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	violation exclusion criteria 2 f. immunocompromised. randomized but not dosed
	C4591001 1131 11311024	1	39	24SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject received vax1 (17AUG2020) but no showed for vax2. Now LTFU
		1	39	24SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Multiple attempts made after no-show for V2,no response.Certified letter sent. Signed 24SEP2020
	C4591001 1133 11331023	2	36	25SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		2	36	25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331037	1	27	26AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
		1	27	26AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331042	1	21	20AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
		1	21	20AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331047	2	8	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject does not want to continue in the study
		2	8	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331052	1	10	12AUG2020	VACCINATION	LOST TO FOLLOW-UP	Certified Letter sent out Subject Lost to Follow up

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	10	12AUG2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter was sent
	C4591001 1133 11331069	2	75	10NOV2020	VACCINATION	LOST TO FOLLOW-UP	Unable to contact subject
		2	75	10NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Site sent certified letter on 10Nov2020
	C4591001 1133 11331087	1	7	14AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
		1	7	14AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331119	2	49	10NOV2020	VACCINATION	LOST TO FOLLOW-UP	Unable to contact subject
		2	49	10NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Site sent certified letter on 10Nov2020
	C4591001 1133 11331122	1	20	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject was called because he was not complying with the diary. Subject withdrew consent
		1	20	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331138	1	24	04SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject stated she is not happy with the study number of visits, number of vaccines, payments.
		1	24	04SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject stated she is not happy with the study number of visits, number of vaccines, payments.
	C4591001 1133 11331162			14AUG2020	SCREENING	OTHER	DELAY CRITERIA MET
				05OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1133 11331170	1	67	19OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HYPERTENSION
		1	67	19OCT2020	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1133 11331177	2	68	10NOV2020	VACCINATION	LOST TO FOLLOW-UP	Unable to contact subject
		2	68	10NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Site sent certified letter on 10Nov2020
	C4591001 1133 11331207	1	43	30SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		1	43	30SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331291	1	47	12OCT2020	VACCINATION	LOST TO FOLLOW-UP	Certified letter sent on 12/OCT/2020
		1	47	12OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent on 12/OCT/2020
	C4591001 1133 11331294	2	54	10NOV2020	VACCINATION	LOST TO FOLLOW-UP	Site sent certified letter on 10Nov2020
		2	54	10NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Site sent certified letter on 10Nov2020
	C4591001 1133 11331295	1	44	09OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		1	44	09OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331338	1	50	17OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent



### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	50	17OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331341	1	45	12OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject is LTF. Certified letter sent 12/OCT/20
		1	45	12OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT IS LTF. CERTIFIED LETTER SENT 12/OCT/20
	C4591001 1133 11331348	2	51	10NOV2020	VACCINATION	LOST TO FOLLOW-UP	Site sent certified letter on 10Nov2020
		2	51	10NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Site sent certified letter on 10Nov2020
	C4591001 1133 11331499	2	17	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject does not wish to continue with study,he asked us to please do notcall him again.
		2	17	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject does not want to be contacted anymore
	C4591001 1133 11331509	1	26	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	Unable to contact subject
		1	26	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact subject
	C4591001 1133 11331510	1	20	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject doesn't feels comfortable receiving the second vaccine.
		1	20	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT DOES NOT FEEL COMFORTABLE RECEIVING 2ND VACCINE. Subject wishies to no longer be contacted.
	C4591001 1133 11331512	1	26	20OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Meets exclusion 5

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1134 11341033	1	35	14SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Dropped
		1	35	14SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1134 11341153	1	2	25AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ABDOMINAL DISCOMFORT
		1	2	25AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DIARRHOEA
		1	2	25AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/EYE PAIN
		1	2	25AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/FATIGUE
		1	2	25AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HEADACHE
		1	2	25AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/MUSCULAR WEAKNESS
	C4591001 1134 11341174	1	5	30AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HEADACHE
		1	5	30AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE PAIN
		1	5	30AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PAIN IN EXTREMITY
	C4591001 1134 11341210	2	1	18SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject is lost to follow up
		2	1	18SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject is lost to follow up
	C4591001 1135 11351061	1	57	02OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		1	57	02OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1135 11351132	2	38	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject contact attempted several times, certified letter mailed on 08OCT2020.
		2	38	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject lost to follow-up
	C4591001 1135 11351199	1	39	01OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up, certified letter sent to patient.
		1	39	01OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject lost to follow-up, certified letter sent
	C4591001 1135 11351200	1	54	16OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up, certified letter sent to patient.
		1	54	16OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject lost to follow-up, certified letter was sent
	C4591001 1135 11351212	1	35	28SEP2020	VACCINATION	LOST TO FOLLOW-UP	patient was lost to follow up. certified letter was sent.
		1	35	28SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject lost to follow-up, certified letter was sent
	C4591001 1135 11351389			19SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	during screening visit, subject withdrew consent after randomization
	C4591001 1135 11351420	1	27	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter sent 19OCT2020
		1	27	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter sent on 19OCT2020
	C4591001 1135 11351428	1	27	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter was sent on 19OCT2020
		1	27	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter was sent on 19OCT2020

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1135 11351430	1	26	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter sent on 19OCT2020
		1	26	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter sent on 19OCT2020
	C4591001 1135 11351523	1	18	10NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		1	18	10NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1136 11361045	1	75	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Unable to contact subject after multiple attempts and certified letter sent
		1	75	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact subject after multiple attempts and certified letter.
	C4591001 1140 11401177	2	54	03NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT CONSIDERED WITHDRAWING CONSENT
		2	54	03NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent via phone on 03Nov2020
	C4591001 1140 11401306	1	23	13NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/AMNESIA
		1	23	13NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PARAPARESIS
	C4591001 1141 11411146	1	50	16OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject no longer meets eligibility criteria. Exclusion #5
	C4591001 1141 11411164	1	58	29OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject declined second vaccination

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1142 11421084	2	62	04NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued d/t medical history discovered after enrollment per instructions of CRA
	C4591001 1147 11471035	1	49	23SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Meets exclusion criterion 5
	C4591001 1147 11471212	1	21	23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		1	21	23SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1149 11491005	1	21	25AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient will be out of state for a long period of time so unable to return for study visits
		1	21	25AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	pt withdrew consent from study. unable to return for visits due to upcoming scheduling conflicts
	C4591001 1149 11491007	2	18	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent and no longer wishes to continue in study citing personal reasons
		2	18	11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent and no longer wishes to participate in the study due to personal reasons
	C4591001 1149 11491031	1	68	16OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up left several VM and certified letter send 09oct2020.
		1	68	16OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient has been unresponsive to repeated site contacts via phone, email and certified letter
	C4591001 1149 11491065	1	31	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	pt is withdrawing consent from study due to personal reasons
		1	31	11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent and does not wish to continue in study citing personal reasons

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1149 11491066	1	78	28OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject was asymptomatic and tested positive for COVID-19 by outside provided.
	C4591001 1149 11491067	1	21	01SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient withdrew consent from the study
		1	21	01SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent and no longer wishes to participate in the study
	C4591001 1149 11491230	1	60	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject sent LTFU certified letter 30OCT2020.
		1	60	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is non responsive. Certified letter sent 30OCT2020.
	C4591001 1152 11521030	1	22	02SEP2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1152 11521034	1	41	21SEP2020	VACCINATION	LOST TO FOLLOW-UP	Several phone messages were left for subject. Certified letter was sent.
		1	41	21SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent; return receipt received back signed by someone other than the subject.
	C4591001 1152 11521043	2	10	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Now has 2 jobs and has no time to do study.
		2	10	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrawal by subject due to time constraints.
	C4591001 1152 11521077	2	1	03SEP2020	VACCINATION	OTHER	Subject had both vaccinations and then moved out of state. No Visit 3 was or ever will be done.
		2	33	05OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT MOVED TO ARIZONA

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1152 11521085	1	8	26AUG2020	VACCINATION	DEATH	DEATH
		1	8	26AUG2020	FOLLOW-UP	DEATH	DEATH
	C4591001 1156 11561006	1	20	08SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria 5
	C4591001 1156 11561015	1	39	28SEP2020	VACCINATION	PREGNANCY	PREGNANCY
	C4591001 1156 11561033	1	16	10SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria 5
	C4591001 1157 11571003	1	56	06OCT2020	VACCINATION	LOST TO FOLLOW-UP	All attempts to contact subject have not been successful.
		1	56	06OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	All attempts to contact subject have been unsuccessful
	C4591001 1157 11571070	1	38	01OCT2020	VACCINATION	LOST TO FOLLOW-UP	All attempts to contact subject have been unsuccessful
		1	38	01OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	All attempts to contact subject have been unsuccessful
	C4591001 1157 11571077	2	30	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject W/C due to moving
		2	30	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Voluntary withdrawal not due to an AE or SAE
	C4591001 1157 11571135	1	23	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Voluntary withdrawal not due to an adverse event
		1	23	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Voluntary withdrawal not due to an AE or SAE

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1161 11611002	1	85	23OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion 5
	C4591001 1161 11611008	1	103	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1161 11611023	1	72	13OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject had several contact attempts by site along with certified letter. Unable to contact subject.
		1	72	13OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	cert. letter sent and signed by subject. unable to contact and subject has not called site.
	C4591001 1161 11611024	1	25	27AUG2020	VACCINATION	LOST TO FOLLOW-UP	unable to contact subject. certified letter returned, no response from subject
	C4591001 1162 11621005	1	32	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject prematurely withdrew from study.
		1	32	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject prematurely withdrawn from study.
	C4591001 1162 11621024			06AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Randomized in error
	C4591001 1162 11621074	2	73	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject LTFU after multiple contact attempts.
	C4591001 1162 11621080	2	64	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU
		2	64	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU



### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1162 11621118	1	35	16SEP2020	VACCINATION	LOST TO FOLLOW-UP	SUBECT WITHDREW,CERTIFIED LETTER SENT 9/16/2020
		1	35	16SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject withdrew from study
	C4591001 1162 11621137	2	66	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU after multiple contact attempts.
	C4591001 1162 11621164	2	66	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU after multiple contact attempts.
	C4591001 1162 11621294	1	60	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU after many contact attempts
		1	60	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU after many contact attempts
	C4591001 1162 11621310	1	60	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU
		1	60	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU
	C4591001 1162 11621374	1	54	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU
		1	54	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU after many contact attempts.
	C4591001 1162 11621477			30SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	Randomized in error
	C4591001 1163 11631059	1	2	08AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/UPPER BODYRASH DUE TO VACCINE@@
	C4591001 1163 11631069	1	66	14OCT2020	VACCINATION	OTHER	REHAB

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1163 11631123	2	58	04NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		2	58	04NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1166 11661037	2	37	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject refused further procedures.
		2	37	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient refused further study procedures. Updated per DM.
	C4591001 1166 11661047	1	1	31AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DIZZINESS
	C4591001 1167 11671003			14AUG2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Did not meet inclusion criteria #3
	C4591001 1167 11671111	1	38	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject is lost to follow up tried multiple calls and certified letter
		1	38	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	no answer after multiple calls and sent certified letter
	C4591001 1168 11681030			15AUG2020	SCREENING	OTHER	randomized in error
				15AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	subject randomized in error
	C4591001 1168 11681070	2	29	02NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Pt. will no longer complete study visits due to her schedule and withdrew consent to participate
		2	29	02NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt would not return for visits as required and chose to no longer participate Verbal WOC

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1168 11681077	2	28	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	PATIENT WITHDREW CONSENT
		2	28	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew consent
	C4591001 1168 11681097	2	1	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject is unable to complete V3 due to his work. Pt will complete the rest of the study visits
	C4591001 1168 11681104	1	70	05NOV2020	VACCINATION	LOST TO FOLLOW-UP	multiple attempts to reach patient for missed Visit 2 and no response.
		1	70	05NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts to reach patient after missed Visit 2 and no response.
	C4591001 1168 11681178	2	34	10NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	The patient chose to no longer participate due to distance and an assumption of placebo group
		2	34	10NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the subject withdrew consent to participate
	C4591001 1169 11691058	1	17	02OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Covid +
	C4591001 1170 11701311	1	33	16OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject contacted multiple times, never responded.
		1	33	16OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow-up subjects subject didnt come for visit.
	C4591001 1171 11711004	2	29	28SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject stated they do not want to participate in the study anymore. Subject withdrew consent.
		2	29	28SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject stated they do not want to participate in the study anymore. Subject withdrew consent.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1171 11711042	1	39	24SEP2020	VACCINATION	LOST TO FOLLOW-UP	Per PI instructions subject LTFU
		1	39	24SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Per PI instructions subject LTFU
	C4591001 1171 11711072	1	37	24SEP2020	VACCINATION	LOST TO FOLLOW-UP	Per PI instructions subject is LTFU
		1	37	24SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Per PI instructions subject LTFU
	C4591001 1171 11711131	1	45	09OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU.
		1	45	09OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Per PI instructions, subject LTFU.
	C4591001 1171 11711159	1	39	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	Per PI, subject LTFU.
		1	39	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Per PI, subject LTFU
	C4591001 1177 11771139	1	74	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
		1	74	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up
	C4591001 1178 11781107	1	22	25SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/LYMPHADENOPATHY
	C4591001 1179 11791138	1	11	03NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5. VAX2 is not given but FUP will be completed.
	C4591001 1194 11941061	1	8	26OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criterion 5

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1195 11951061	1	21	06NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient withdrawal consent. she is afraid about the second vaccination
	C4591001 1203 12031037	1	6	26OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Covid-19 Illness between V1 and V2(Positive self swab+symptoms) no 2ndvaccination administered.
	C4591001 1204 12041197†	1	37	13NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Participant has chosen to withdraw from the study.
	C4591001 1205 12051028			30OCT2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/BLOOD PRESSURE INCREASED
	C4591001 1207 12071024	1	17	13NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Participant symptomatic COVID +
	C4591001 1209 12091013	1	9	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5. VAX2 is not given but follow-up will be completed
	C4591001 1212 12121023			03NOV2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	After PI judgement, subject was not vaccinated.
	C4591001 1217 12171044	1	7	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1223 12231200			21SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	subject randomized in error
	C4591001 1223 12231234			12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject left the site before vaccination 1

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1224 12241009	1	37	18SEP2020	VACCINATION	LOST TO FOLLOW-UP	PT failed to attend V2; site attempted contact via phone and certified letter
		1	37	18SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	PT failed to return for V2; site attempted contact via phone and certified letter
	C4591001 1224 12241065	1	13	05SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HEART RATE IRREGULAR
		1	13	05SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1226 12261072	1	22	01SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/MYALGIA
	C4591001 1226 12261108	2	32	01OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Participant withdrew consent for not wanting to comply with the study procedures.
		2	32	01OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal by subject
	C4591001 1226 12261205	2	51	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not want to continue in the study.
	C4591001 1226 12261272	2	28	07OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject withdrew consent due unavailability.
		2	28	07OCT2020	FOLLOW-UP	REFUSED FURTHER STUDY PROCEDURES	REFUSED FURTHER STUDY PROCEDURES
	C4591001 1226 12261409	1	44	07OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject did not want to continue in the studies procedures.
		1	44	07OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject has no more availability to continue in the study.

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1226 12261894	1	5	29SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	The subject had a RT-PCR test COVID-19, so he was discontinued from the study, not receiving the V2.
	C4591001 1226 12262108	1	20	27OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1226 12262189	1	14	27OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1226 12262267	1	2	18OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criteria 5
	C4591001 1229 12291204	1	30	11NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
	C4591001 1230 12301045†	1	22	20OCT2020	VACCINATION	PREGNANCY	PREGNANCY
	C4591001 1230 12301148	1	23	28OCT2020	VACCINATION	OTHER	Patient confirmed re-location for work purposes not foreseen. Not able to attend study visits
		1	23	28OCT2020	FOLLOW-UP	OTHER	Participant relocated and cannot attend study procedures.
	C4591001 1230 12301150	1	23	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew their consent.
		1	23	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject cannot commit to all the study procedures.
	C4591001 1231 12311031	1	37	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12311054	1	45	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject refers that the decision to stop participating in the study is due to lack of time
		1	45	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	No time necessary to comply with the visits and the demand that it takes to participate in the study
	C4591001 1231 12311087	1	39	19SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
		1	39	19SEP2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued due to previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311088	1	48	28SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311125	1	23	04SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Participants who, in the judgment of the investigator, are at risk for acquiring COVID-19
	C4591001 1231 12311147	1	7	19AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311189	1	39	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311191	1	32	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311195	1	40	22SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311200	1	22	04SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not sign amendment 5 because he did not agree



### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	22	04SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the subject did not sign amendment 5 because he did not agree
	C4591001 1231 12311356	1	64	17OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer did not specify the reason why she decided to stop participating.
		1	64	17OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The volunteer did not specify the reason why she decided to stop participating.
	C4591001 1231 12311374	1	31	14SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
		1	31	14SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
	C4591001 1231 12311391	1	14	28AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	COVID 19 DIAGNOSIS
		1	80	02NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up after several tries of contact
	C4591001 1231 12311402	1	30	13SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311409			25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the subject decided to withdraw the consent.
	C4591001 1231 12311431	1	27	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject is afraid of exposure to COVID-19 in next study visits
		1	27	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	you fear going to a health institution and that this will expose you to be reinfected by SARS-COV2
	C4591001 1231 12311441	1	28	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	for having moved to Gualeguaychu (Province of Entre Rios)

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	28	11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	for having moved to Gualeguaychu (Province of Entre Rios)
	C4591001 1231 12311443	1	27	10SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Codiv 19 positive
	C4591001 1231 12311473	1	29	12SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311516			13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	does not want to continue with the controls, after informing you that it was discontinued.
	C4591001 1231 12311532	1	23	07SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311557	2	46	19OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	He believes that received a placebo and therefore has no interest in continuing with further control
		2	46	19OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject THINKS received placebo, so withdrew consent
	C4591001 1231 12311559	1	28	12SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
		1	28	12SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject decided to withdraw consent
	C4591001 1231 12311568	1	37	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311577	2	57	02NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12311641	1	29	13SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311656	1	40	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311816	1	31	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311911	1	38	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311926			18AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/SYNCOPE
	C4591001 1231 12311973	2	43	20OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer communicated his desire to withdraw consent to participate in the study when the alarm
		2	43	20OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The volunteer communicated his desire to withdraw consent to participate in the study when the alarm
	C4591001 1231 12311991	1	21	07SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject decided to withdraw consent
		1	21	07SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject decided to withdraw consent
	C4591001 1231 12311996	2	60	06NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to going to live abroad.
	C4591001 1231 12312176			19AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized for error

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12312186	2	35	13OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal and work issues.
		2	35	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal and work issues.
	C4591001 1231 12312244	1	23	10SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312284	1	22	09SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312320	1	61	18OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject with previous clinically or microbiological diagnosis of COVID-19
	C4591001 1231 12312326	1	34	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312334	1	32	19SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312339	1	38	25SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312361	1	68	25OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Inability to attend visits for work reasons
		1	68	25OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdraw consent due to personal reasons
	C4591001 1231 12312365	1	28	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	56	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject decided to withdraw consent due to lack of time
	C4591001 1231 12312375	1	26	13SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312403	1	24	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The patient does not want to take the second dose.
	C4591001 1231 12312451	1	23	11SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Participants who are willing and able to comply with all scheduled visits, vaccination plan, lab...
	C4591001 1231 12312483			20AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	subject randomized in error
	C4591001 1231 12312559	1	23	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject is available to attend the protocol visits
	C4591001 1231 12312577	1	9	28AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/METASTASES TO CENTRAL NERVOUS SYSTEM
	C4591001 1231 12312594	1	77	04NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Stop participating for personal reasons
		1	77	04NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdraws his consent for personal reasons
	C4591001 1231 12312660	1	56	14OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312713	2	35	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reason.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12312752	1	40	29SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312759	2	36	16OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the volunteer reported her desire to withdraw consent to participate in the study
		2	36	16OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the volunteer reported her desire to withdraw consent to participate in the study
	C4591001 1231 12312763	1	35	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312848	1	29	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdraws consent. Subject declares she does not want to be part of the research study
		1	29	18SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdraws consent. Subject declares she does not want to be part of the research study
	C4591001 1231 12312916	1	20	09SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19.
	C4591001 1231 12312982	2	15	23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
		2	15	23SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrawal of consent for personal reasons
	C4591001 1231 12313006	1	21	10SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313030	2	37	16OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The decision to stop participating is due to personal reasons.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		2	37	16OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The decision to stop participating is due to personal reasons.
	C4591001 1231 12313068	1	23	13SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313069	1	35	25SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313115	1	20	10SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313125	1	24	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313175	1	32	22SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject refuses to receive the second dosis of the investigation product
	C4591001 1231 12313207	1	21	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer wishes to have a child with his current partner in the short term
		1	21	11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the volunteer wants to have a child in the short term
	C4591001 1231 12313211	1	11	01SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19.
	C4591001 1231 12313225	1	20	10SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313357	1	20	11SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12313376	1	22	13SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	being written phase 2/3 does not assure you that the safety of the product has been fully evaluated
		1	22	13SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	being written phase 2/3 does not assure you that the safety of the product has been fully evaluated
	C4591001 1231 12313395	1	23	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313428	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The patient decided not to apply the second dose.
	C4591001 1231 12313443			23AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	randomized, no vaccinated
	C4591001 1231 12313449	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject refused to receive the second dose due to the previous medication dosis error.
	C4591001 1231 12313459	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject made the decision not to receive the second vaccination
	C4591001 1231 12313467	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time, but will continue in the study
	C4591001 1231 12313469	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not want to receive a second dose but did continue in the study
	C4591001 1231 12313479	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject decided not to received second dose of the investigational product
	C4591001 1231 12313486	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time, but will continue in the study



### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12313492	1	28	19SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time, but will continue in the study
	C4591001 1231 12313497	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time, but will continue in the study
	C4591001 1231 12313498	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time, but will continue in the study
	C4591001 1231 12313506	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject refused to receive the second dose of treatment due to medication error in the first dose.
	C4591001 1231 12313509	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject did not agree to receive the second dose of the vaccine but continues in the Study
	C4591001 1231 12313510	1	48	09OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criteria: Previous diagnosis (clinical or microbiological) of COVID-19
	C4591001 1231 12313512	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject refused to receive the second dose of the treatment due to the medication error
	C4591001 1231 12313514	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject declined to receive the second vaccination
	C4591001 1231 12313517	1	27	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject declined to receive the second vaccination
	C4591001 1231 12313518	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Did not accept to receive second dose but accept continue with the rest of study procedures

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12313519	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Did not accept to receive second dose but accept continue with the rest of study procedures
	C4591001 1231 12313527			02OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject declined from receiving the investigation product
	C4591001 1231 12313528	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject declined to receive the second vaccination
	C4591001 1231 12313534	1	28	19SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	medication error in V1, the subject decided not to vaccinate in V2
	C4591001 1231 12313537	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	medication error in V1, subject decided not to vaccinate in V2
	C4591001 1231 12313541	1	26	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject did not receive the second vaccination but continued otherwise with study procedures
	C4591001 1231 12313546	1	26	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject did not receive the second vaccination but continued otherwise with study procedures
	C4591001 1231 12313551	1	27	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject did not agree to receive the second dose, but continues in the study
	C4591001 1231 12313554	1	28	19SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject did not agree to receive the second dose, but continues in the study
	C4591001 1231 12313567	1	26	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject did not agree to receive the second dose, but continues in the study

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12313592	1	28	19SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19.
	C4591001 1231 12313609	2	44	26OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrawal by subject due to personal (work) issues.
		2	44	26OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal (work) issues.
	C4591001 1231 12313619	2	43	27OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal issues.
		2	43	27OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal issues.
	C4591001 1231 12313622	1	24	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Healthy participants eligible for inclusion in the study and Previous diagnosis of COVID-19
	C4591001 1231 12313657	1	36	28SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313662	1	26	18SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313699	2	44	27OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	wants to leave the study
		2	44	27OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	wants to leave the study
	C4591001 1231 12313709	1	52	14OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12313758	1	44	06OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313823	2	45	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
		2	45	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
	C4591001 1231 12313851	2	40	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Personal reason that he preferred not to share
		2	40	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Personal reason that he preferred not to share
	C4591001 1231 12313869			25AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the volunteer requests that she be withdrawn from the study
	C4591001 1231 12313955	2	30	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to strict personal family causes.
		2	30	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to strict personal family causes
	C4591001 1231 12313981	2	45	29OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The decision to stop participating must be a move to the province of Santiago del Estero.
		2	45	29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The decision to stop participating must be a move to the province of Santiago del Estero.
	C4591001 1231 12314030	2	37	23OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
		2	37	23OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12314134	1	20	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12314179	1	30	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent after visit 1
		1	30	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent after visit 1
	C4591001 1231 12314205	1	20	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Clinical diagnosis of covid 19
	C4591001 1231 12314266	1	22	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
		1	22	16SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
	C4591001 1231 12314314	1	27	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
		1	27	21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature.
	C4591001 1231 12314381	1	55	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not answer phone call or certified letter. Contact is considered lost
		1	55	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject did not answer phone or certified letter. Contact is consider lost
	C4591001 1231 12314385	1	44	09OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	For meeting the exclusion criterion of previous diagnosis, subject discontinued

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12314492	1	20	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12314580	1	33	28SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12314590	1	15	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer states that the decision to stop participating in the study is of a personal nature.
		1	15	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The volunteer states that the decision to stop participating in the study is of a personal nature.
	C4591001 1231 12314700	1	22	18SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12314713	1	22	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject refused to receive second dose of investigation product
	C4591001 1231 12314848	1	20	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
		1	64	30OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	after failed attempts of contact by phone and certified letter, it is consider lost of follow up
	C4591001 1231 12314853	2	43	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	unforeseen move out of the country, with no probable date of return.
		2	43	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	unforeseen move out of the country, with no probable date of return.
	C4591001 1231 12314923	1	31	27SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject not being able to continue attending visits.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	31	27SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject not being able to continue attending visits.
	C4591001 1231 12314964	2	48	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	The volunteer does not answer calls. Contact was lost, the study was withdrawn
		2	48	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	The volunteer does not answer calls. Contact was lost, the study was withdrawn
	C4591001 1231 12314984	1	21	17SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
		1	36	02OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	It is due to having been discontinued from the study.
	C4591001 1231 12315269	1	42	09OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12315308			16SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error
	C4591001 1231 12315357	1	13	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject does not specify the reasons for withdrawing from the study
		1	13	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject does not specify the reasons for withdrawing from the study
	C4591001 1231 12315429	1	37	05OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE PAIN
		1	37	05OCT2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1231 12315441	1	54	22OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DEPRESSION

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12315600	1	22	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject refused to receive second dose of investigation product
	C4591001 1232 12321015	1	21	02SEP2020	VACCINATION	LOST TO FOLLOW-UP	patient is labeled a "no show"
	C4591001 1232 12321037	1	21	02SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient labeled as a "no show"
	C4591001 1232 12321037			18AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject Randomized in Error
	C4591001 1232 12321093	2	29	13OCT2020	VACCINATION	LOST TO FOLLOW-UP	treatment period was not completed
	C4591001 1232 12321094	2	29	13OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Treatment period was not completed
	C4591001 1232 12321094	2	27	13OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject relocated out of state
	C4591001 1232 12321094	2	27	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent
	C4591001 1232 12321100	1	51	15OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	V2 Vaccination was not given due to COVID 19 symptoms present at that time
	C4591001 1232 12321142	1	57	26OCT2020	VACCINATION	LOST TO FOLLOW-UP	due to subject's job she will not be able to attend appointments.
	C4591001 1232 12321142	1	57	26OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1232 12321175	1	51	23OCT2020	VACCINATION	OTHER	Subject did not received Vaccination 2



## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1232 12321213	1	52	30OCT2020	VACCINATION	PREGNANCY	PREGNANCY
	C4591001 1232 12321293	1	22	22OCT2020	VACCINATION	PREGNANCY	PREGNANCY
	C4591001 1235 12351027	1	18	23SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	COVID-19 positive with symptoms. Will not receive Vaccine 2.
	C4591001 1235 12351071	1	9	22SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Will continue follow up, but will not receive vaccine 2.
	C4591001 1235 12351167			09OCT2020	FOLLOW-UP	PROTOCOL DEVIATION	randomized but not vaccinated-met exclusion criteria
	C4591001 1235 12351187	1	9	24OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	meets exclusion #5
	C4591001 1235 12351188	1	7	22OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	positive COVID 19- exclusion #5
	C4591001 1241 12411132	1	2	15AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued.Exc #5
	C4591001 1241 12411144	1	1	17AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued Exc 5
	C4591001 1241 12411260	1	12	30AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued. Exc#5

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1241 12411279	1	23	10SEP2020	VACCINATION	PREGNANCY	PREGNANCY
	C4591001 1241 12411482	1	7	31AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued. RT-PCR SARS Cov-2 Positive
	C4591001 1241 12411688	1	13	27SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued Exc#5
	C4591001 1241 12411695	1	4	18SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued Exc#5
	C4591001 1241 12411766	1	24	09OCT2020	VACCINATION	PREGNANCY	PREGNANCY
	C4591001 1241 12412355	1	22	09NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Discontinued Exc#5
	C4591001 1246 12461025	1	22	19OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/URTICARIA
	C4591001 1247 12471121	2	10	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient withdrew from study after motorcycle accident
	C4591001 1247 12471149	1	1	01OCT2020	VACCINATION	LOST TO FOLLOW-UP	Patient not answering calls from site; possibly relocated
		1	1	01OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Patient not answering calls from site; could possibly have relocated
	C4591001 1247 12471151	1	22	22OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Pt. sold e-diary smart phone. Does not meet eligibility Inclusion 2. E-diary deactivated.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1248 12481018			28AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent
	C4591001 1248 12481025			29AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent
	C4591001 1248 12481046	1	66	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	Missed V2 on 20Sep2020; site has been unable to contact subject despite multiple calls.
		1	66	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Please see EOT page
	C4591001 1248 12481048	1	66	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject missed V2 on 20Sep2020; multiple attempts to reach subject were unsuccessful.
		1	66	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Please see EOT page.
	C4591001 1248 12481060			02SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Participant withdrew consent
	C4591001 1248 12481110	1	59	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject was no show for V2; unable to contact subject.
		1	59	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was no show for V2; unable to contact subject.
	C4591001 1248 12481175	1	22	06OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1248 12481199	1	35	21OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		1	35	21OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1248 12481218			21SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT
				21SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/SYNCOPE
	C4591001 1251 12511095	1	21	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject wished to withdraw from the study
		1	21	21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1251 12511207	1	1	23SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	clinical diagnosis of Covid-19
	C4591001 1254 12541023	1	25	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Per PI, subject no longer meets eligibility criteria by meeting exclusion #1
	C4591001 1254 12541116	1	21	29SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	PATIENT WITHDREW CONSENT
		1	21	29SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject called the site and withdrew consent without any specific reason.
	C4591001 1254 12541142	1	26	07OCT2020	VACCINATION	PREGNANCY	PREGNANCY
	C4591001 1260 12601049			02SEP2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	hypertension after randomization so withdrawn from study
	C4591001 1260 12601070			04SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	pt withdrawal due to pregnancy partner protocol guidelines

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1260 12601126	1	30	16OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient refusing vaccination # 2 at this time but she will continue with the rest of the visits
	C4591001 1264 12641018			25AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew prior to IP administration due to needing MMR booster.
				25AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject randomized but remembered she had an MMR vaccine within last 28 days and would need booster.
	C4591001 4444 44441025	1	12	02OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 4444 44441043	1	19	09OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	diagnosis covid 19 illness
	C4591001 4444 44441044	1	16	06OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Positive COVID-19 Diagnosis
	C4591001 4444 44441048	1	18	08OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Husband is a cancer patient and asked her not to continue for the fear of her going to a hospital
		1	18	08OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Husband is a cancer patient and asked her not to continue for the fear of her going to a hospital
	C4591001 4444 44441079	1	22	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	disagree with not knowing whether to receive placebo or research product
		1	22	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	disagree with not knowing whether to receive placebo or research product
	C4591001 4444 44441135			21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	She does not want to be part of the study due to personal problems.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 4444 44441179	1	22	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal problems.
		1	22	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal problems.
	C4591001 4444 44441224	2	31	12NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	due to the fact that he did not agree to their follow-up for the covid disease
		2	31	12NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	due to the fact that he did not agree to their follow-up for the covid disease
	C4591001 4444 44441273	1	24	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject expressed his decision to stop participating for work reasons.
		1	24	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject expressed his decision to stop participating for work reasons.
	C4591001 4444 44441522	1	21	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	For work reasons he is unable to complete the visits scheduled by protocol
		1	21	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	For work reasons he is unable to complete the visits scheduled by protocol
	C4591001 4444 44441560	1	10	02OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Positive COVID-19 diagnosis.
	C4591001 4444 44441569	1	22	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
		1	22	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
	C4591001 4444 44441572	1	31	23OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Participant who is willing and able to comply with all study procedures

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 4444 44441818	1	28	22OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	He refers not being able to continue with the study due to personal problems.
		1	28	22OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	He refers not being able to continue with the study due to personal problems.
	C4591001 4444 44441931	1	21	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	For recommendation of his doctor.
	C4591001 4444 44441951	1	43	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	30OCT unsuccessful phone call 06NOV registered letter is sent. Still no answer
		1	43	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	30OCT unsuccessful phone call 06NOV registered letter is sent. Still no answer
	C4591001 4444 44441979	1	21	15OCT2020	VACCINATION	PREGNANCY	PREGNANCY
		1	48	11NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to particular reasons
	C4591001 4444 44442107	1	48	13NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	personal motives
		1	48	13NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	personal motives
	C4591001 4444 44442194	1	20	16OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating must be traveled abroad.
		1	20	16OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating must be traveled abroad.
	C4591001 4444 44442263	1	24	20OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Will not be able to continue in the trial since she has had to travel abroad for personal reasons

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	24	20OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Will not be able to continue in the trial since she has had to travel abroad for personal reasons
	C4591001 4444 44442293	1	39	04NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal problems.
		1	39	04NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal problems.
	C4591001 4444 44442319	1	37	02NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Due to a psychiatric condition, subject expresses his desire to withdraw consent
		1	37	02NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Due to a psychiatric condition, subject expresses his desire to withdraw consent
>55	C4591001 1005 10051214	1	11	13SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/FACIAL PAIN
		1	11	13SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/SWELLING FACE
	C4591001 1005 10051403	1	4	07NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	DISCONTINUATION AS SUBJECT TESTED POSITIVE FOR COVID 19
	C4591001 1006 10061020	1	36	16SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/CORONARY ARTERY OCCLUSION
		1	36	16SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1007 10071101	2	63	21OCT2020	FOLLOW-UP	DEATH	DEATH
	C4591001 1007 10071114	1	22	24AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	meets inc #3; Per subI Recent loss of taste & smell, anorexia & dizziness with gait instability



### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1007 10071347	1	22	05NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject did not meet inclusion criteria #3
	C4591001 1008 10081639	1	6	24OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Tested positive for COVID 19
	C4591001 1009 10091020	1	14	24AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	WITHDRAWAL BY SUBJECT
		1	14	24AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	WITHDRAWAL BY SUBJECT
	C4591001 1009 10091157	1	21	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		1	21	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1011 10111181	1	1	08OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PARAESTHESIA ORAL
	C4591001 1012 10121149	1	53	30OCT2020	VACCINATION	LOST TO FOLLOW-UP	No call now show for two scheduled appointments and no response to certified letter sent.
		1	53	30OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	No call, no show for 2 scheduled visits and no response to certified letter
	C4591001 1013 10131097			06AUG2020	SCREENING	OTHER	SUBJECT WAS ALREADY RANDOMIZED BUT DID NOT MEET CRITERIA FOR VACCINATION. SUBJECT IS DISCONTINUED.
				06AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT DID NOT MEET EXCLUSION #5 BUT WAS ALREADY RANDOMIZED INTO STUDY. DID NOT RECEIVE VACCINATION.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1013 10131123	2	70	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	UNKNOWN
		2	70	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	UNKNOWN
	C4591001 1013 10131192	1	23	08SEP2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		1	23	08SEP2020	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1013 10131509	2	29	29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT FROM THE STUDY.
	C4591001 1019 10191033			13AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent after being randomized.
	C4591001 1019 10191201	1	50	30OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject was still enrolled in another study while being enrolled in this one.
	C4591001 1019 10191300			22OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent after being randomized.
				22OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent after being randomized.
	C4591001 1022 10221015			17AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient changed his mind after randomization but before vaccination
	C4591001 1022 10221057			25AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew IFC.
	C4591001 1022 10221150			09SEP2020	FOLLOW-UP	OTHER	IP was quarantined after patient was randomized

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1024 10241077	1	28	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent, will not return to clinic for any visits/procedures- wants no contact
		1	28	21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1024 10241130†	1	9	28OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	patient no longer qualifies for vacc#2 due to meeting exclusion criteria #5
	C4591001 1027 10271206†	1	31	30OCT2020	VACCINATION	LOST TO FOLLOW-UP	Site attempted to contact subject on multiple occasions and certified letter was sent.
		1	31	30OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Site attempted to contact subject on multiple occasions and certified letter was sent.
	C4591001 1037 10371057			24AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT NOT WILLING TO ATTEND VISITS AFTER RANDOMIZATION WAS COMPLETED
	C4591001 1037 10371117			18SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not want to wait to receive Flu vaccine
	C4591001 1039 10391019	1	24	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Due to previous medical condition, patient now requires treatment with corticosteroid.
	C4591001 1042 10421010	1	21	19AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent
		1	21	19AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1044 10441113			11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent to participate

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1046 10461259	1	22	05OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject Decision to With Draw
		1	22	05OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Decision
	C4591001 1047 10471011	2	11	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		2	11	18SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1047 10471252	1	22	12OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	The subject was diagnosed and had symptomatic Covid
	C4591001 1052 10521020	1	21	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrawl by subject
		1	21	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawl by patient
	C4591001 1052 10521062	1	26	25SEP2020	VACCINATION	LOST TO FOLLOW-UP	n/a
		1	26	25SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	los to follow up
	C4591001 1054 10541071			28AUG2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	Re-screened and randomized as subj 10541083.
	C4591001 1054 10541175			21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent due to personal reasons
	C4591001 1054 10541186	1	1	23SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DIZZINESS

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	1	23SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/NAUSEA
	C4591001 1055 10551039	1	23	04SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject willing to continue in study off medication
	C4591001 1056 10561018	1	19	09SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT STATED SHE DOES NOT WANT TO CONTINUE HER PARTICIPATION IN THE STUDY.
		1	19	09SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1056 10561078			28AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt. referred she did not want to continue in the study.
	C4591001 1056 10561079	1	55	21OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT STATED SHE IS SCARED OF THE VACCINE AFTER WATCHING NEWS REPORT ABOUT SAFETY CONCERNS.
		1	55	21OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT STATED SHE IS SCARED OF THE VACCINE AFTER WATCHING NEWS REPORT ABOUT SAFETY CONCERNS.
	C4591001 1056 10561083	2	30	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	PT STATED HE HAS TO LEAVE THE COUNTRY DUE TO A PERSONAL EMERGENCY ANDHE WILL NOT BE ABLE TO CONTINUE
		2	30	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	PT STATED HE HAS TO LEAVE THE COUNTRY DUE TO A PERSONAL EMERGENCY ANDHE WILL NOT BE ABLE TO CONTINUE
	C4591001 1056 10561120	1	25	25SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject expressed his desire to withdrew his participation in the trial.
		1	25	25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject expressed his desire to withdrew his participation in the trial.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1056 10561123	1	24	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject states he doesn't want to continue in the study.
		1	24	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject states he doesn't want to continue in the study.
	C4591001 1056 10561275	1	51	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
		1	51	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
	C4591001 1056 10561276	1	20	06OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT STATED HE DOES NOT WANT TO CONTINUE PARTICIPATING IN THE TRIAL.
		1	20	06OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT STATED HE DOES NOT WANT TO CONTINUE PARTICIPATING IN THE TRIAL.
	C4591001 1056 10561298	1	50	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
		1	50	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
	C4591001 1056 10561371	1	38	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
		1	38	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject lost to follow up after several unsuccessful attempts to contact.
	C4591001 1066 10661128	1	20	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	discontinued/refused vaccination #2
	C4591001 1066 10661350	1	16	03NOV2020	VACCINATION	DEATH	DEATH

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	16	03NOV2020	FOLLOW-UP	DEATH	DEATH
	C4591001 1071 10711023	1	12	23AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/CORONARY ARTERY DISEASE
		1	17	28AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1071 10711063	1	13	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		1	13	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1071 10711169	1	31	15OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ALCOHOL POISONING
		1	31	15OCT2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1071 10711216	1	5	13OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	SUBJECT HAD POSITIVE COVID TEST PRIOR TO VISIT 2
	C4591001 1072 10721065	1	22	18SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrawal by subject
		1	22	18SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal by subject
	C4591001 1079 10791057	1	38	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject is lost to follow up
		1	38	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject is lost to follow up
	C4591001 1080 10801064	1	50	07OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient did not wish to receive Vax2 but agreed to continue in study.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1082 10821029	2	1	25AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject completed vaccination 2 but did not complete the 1 month follow-up.
		2	29	22SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject completed vaccination 2 but did not complete the 1 month follow-up.
	C4591001 1082 10821062			06AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject was randomized but did not receive study vaccination. Subject left site prior to vaccination
	C4591001 1082 10821126	1	1	21AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent prior to receiving the second vaccination.
		1	33	22SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not complete follow-up period.
	C4591001 1082 10821164	1	25	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject believes that his first vaccine is what caused him to be COVID +.
		1	25	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject believes that his first vaccine is what caused him to be COVID +.
	C4591001 1083 10831173	1	68	02NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1084 10841180	2	53	26OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject dropped from trial
		2	53	26OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew from trial
	C4591001 1084 10841184	2	53	26OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew from trial
		2	53	26OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew from trial



### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1084 10841366			09SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject left during vaccine prep, was called and texted w/o response. Dropped from study.
	C4591001 1084 10841446			25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew from trial
	C4591001 1087 10871080	1	44	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrew consent d/t frustrations with limitations of double-blind study.
		1	44	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent d/t frustrations with limitations of double-blind study.
	C4591001 1087 10871121	1	22	09SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/GASTROINTESTINAL HAEMORRHAGE
		1	22	09SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1087 10871211	1	24	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrawal of consent to participate in study due to not being able to get cash off of the ClinCard.
		1	24	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrawal of consent to participate in study due to not being able to get cash off of the ClinCard.
	C4591001 1087 10871228	1	22	16SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/CARDIAC FAILURE CONGESTIVE
		1	22	16SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1087 10871434			11SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt withdrew consent noting it would be very difficult to ever collect blood from her.
	C4591001 1087 10871505	1	23	13OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Pt reports she has a lot going on in her personal life & wishes to discontinue study.

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	23	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt reports she has a lot going on in her life & wishes to discontinue study.
	C4591001 1087 10871512			22SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error
	C4591001 1089 10891098	2	30	29SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject came by office an not longer wanted to do trial. returned diary
		2	30	29SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject came by office an not longer wanted to do trial. returned diary
	C4591001 1089 10891344	1	35	26OCT2020	VACCINATION	LOST TO FOLLOW-UP	contacts attempted and certified letter sent
		1	35	26OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	several attempts have been made to contact subject and certified letter sent. LTFU
	C4591001 1090 10901141	2	9	08SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	pt is moving away and not able to come to visits any longer. He talked to PI
		2	9	08SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject moved away
	C4591001 1090 10901415	1	58	13NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HEADACHE
	C4591001 1091 10911092			10AUG2020	FOLLOW-UP	OTHER	subject randomized with incorrect subject demographics, was not dosed, then withdrawn and rescreened
	C4591001 1092 10921191	1	35	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not show for visit 2 unable to make contact with subject
		1	35	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not return for V2

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1092 10921268	1	5	26OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject tested positive for COVID-19 and meets EC #5
	C4591001 1093 10931050	1	24	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	PER PROTOCOL, PT WILL NOT RECEIVE SECOND VAX DUE TO POSITIVE COVID (SYMPTOMATIC), WILL STILL CONTINUE
	C4591001 1094 10941080	1	24	25SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrawal of consent by subject
		1	24	25SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal of consent by patient
	C4591001 1094 10941130	1	32	16OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		1	32	16OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1095 10951102	1	35	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Unwilling to come back for appt at this time. Participant did not verbalize withdrawing consent
		1	35	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Unwilling to come back for appt at this time. Participant did not verbalize withdrawing consent
	C4591001 1095 10951107	2	33	28SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	due to ongoing medical issues
	C4591001 1095 10951108	2	33	28SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	participant withdrew to care for husbands ongoing medical needs
	C4591001 1096 10961048	1	28	14SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	28	14SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent
	C4591001 1096 10961082	1	54	12OCT2020	VACCINATION	LOST TO FOLLOW-UP	LTFU, unresponsive to contact attempts
		1	54	12OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	site unable to contact subject after multiple attempts and certified letter sent
	C4591001 1096 10961086	1	52	11OCT2020	VACCINATION	LOST TO FOLLOW-UP	LTFU, unresponsive to contact attempts
		1	52	11OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	LTFU, unresponsive to contact attempts
	C4591001 1096 10961160	1	47	13OCT2020	VACCINATION	LOST TO FOLLOW-UP	unable to reach subject despite numerous attempt and certified letter was sent
		1	47	13OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to reach subject despite numerous attempt and certified letter was sent
	C4591001 1097 10971003			17AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Randomized in error.
	C4591001 1097 10971033	1	23	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient decided that he no longer wanted to be involved in the trial.
		1	23	16SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt decided that he no longer wanted to be involved in the trial.
	C4591001 1098 10981026	2	33	26OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject no longer wanted to participate in the study.
		2	33	26OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	no reason given.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1098 10981030	1	17	06SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject Withdraw consent and no longer interested in participating in research trial.
		1	17	06SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent because he beleived site has infected him with Covid-19 .
	C4591001 1098 10981092			03SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawl
	C4591001 1098 10981109			04SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject unable to be compliant and comit to schedule visitand vaccination plans.
	C4591001 1098 10981130	2	30	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew the consent , as he was will be not able to be compliant in the future.
		2	30	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew the consent , as he was will be not able to be compliant in the future.
	C4591001 1109 11091093	2	45	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject never return for visit, returned call or returned certified letter.
		2	45	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject never return for visit, returned call or returned certified letter.
	C4591001 1109 11091095	2	37	29SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject called site and withdrew consent today.
		2	37	29SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject called site and withdrew consent today.
	C4591001 1109 11091248	1	25	09SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT CALLED WHEN V-2 WAS MISSED AND SHE STATED NO LONGER WANTING TO PARTICIPATE.

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	25	09SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT CALLED WHEN V-2 WAS MISSED AND SHE STATED NO LONGER WANTING TO PARTICIPATE.
	C4591001 1109 11091253	2	46	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT
		2	46	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT
	C4591001 1109 11091259			16AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Randomized in error
	C4591001 1109 11091475	1	51	29OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO CALLS OR CERTIFIED LETTER
		1	51	29OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO CALLS OR CERTIFIED LETTER
	C4591001 1109 11091503	1	20	30SEP2020	VACCINATION	ADVERSE EVENT	Subject declined second vaccine however is willing to continue followup if approved by sponsor./ABDOMINAL PAIN UPPER
	C4591001 1111 11111112	2	32	05OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent verbally due to no longer wanting to participate
		2	32	05OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrawal
	C4591001 1112 11121052	1	50	22SEP2020	VACCINATION	LOST TO FOLLOW-UP	unable to reach subject for follow up visits
		1	50	22SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to reach subject to return for follow up visits
	C4591001 1112 11121118	1	2	12AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/TACHYCARDIA

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1112 11121134	1	38	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject no longer wishes to continue
		1	38	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject does not wish to continue in study
	C4591001 1112 11121255	1	2	07OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/CHILLS
		1	2	07OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HEADACHE
		1	2	07OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PYREXIA
	C4591001 1112 11121337	1	6	26OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/FATIGUE
		1	6	26OCT2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/DIARRHOEA
	C4591001 1116 11161117			03SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	ICF Withdrawn
	C4591001 1116 11161118			03SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	ICF Withdrawn
	C4591001 1116 11161253	1	11	28SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient was symptomatic and tested positive for COVID-19 between Vaccine 1 and Vaccine 2
	C4591001 1118 11181065	1	50	07OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent prior to coming in for visit 2 after visit 2 was missed multiple times
		1	50	07OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject missed visit 2 appointment and has not returned any contact attempts from the site.
	C4591001 1118 11181072	1	54	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Refused vaccination 2, consents to follow-up study procedures (blood draws, diary, phone calls)

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1118 11181090	2	21	05OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent
		2	21	05OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	WITHDREW CONSENT
	C4591001 1120 11201066	1	66	09OCT2020	VACCINATION	LOST TO FOLLOW-UP	UNABLE TO BE REACHED FOR VISIT 2
		1	66	09OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject phone disconnected emergency contact can't be reached and certified letter sent no response
	C4591001 1120 11201073	1	24	28AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject refused vax 2. will follow subject throughout duration of study
	C4591001 1120 11201127	1	4	14AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DIARRHOEA
		1	4	14AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1120 11201182	2	37	09OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject stated he wanted to withdraw
		2	37	09OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject stated he wanted to withdraw
	C4591001 1120 11201335	1	11	26OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5 VAX2 is not given but FUP will be completed
	C4591001 1120 11201408	1	2	29OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DEPRESSION
	C4591001 1125 11251211	1	53	02NOV2020	VACCINATION	OTHER	did not receive 2nd vax



### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1125 11251222	1	9	05NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5.
	C4591001 1128 11281023			01AUG2020	FOLLOW-UP	OTHER	unable to obtain lab sample, therefore subject was discontinued
	C4591001 1128 11281109			12AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject changed his mind regarding participation in the Covid clinical trial
	C4591001 1128 11281212	2	33	19OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		2	33	19OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT TO PROCEED IN STUDY
	C4591001 1129 11291082			10AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	randomized but not dosed. failed exclusion criteria g. bleeding condition
	C4591001 1129 11291117			17AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	failed exclusion criteria L. - participation in other studies. randomized but not dosed
	C4591001 1133 11331080	2	49	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		2	49	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331168	2	34	07OCT2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		2	34	07OCT2020	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1133 11331174	2	57	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject refuse to be compliant with diary. He is not longer interesting in study.
	C4591001 1133 11331197			19AUG2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	subject received shingle vaccine on 7/22/2020, subject was not dosed
	C4591001 1133 11331426	1	34	12OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT IS LTF. CERTIFIED LETTER SENT 12/OCT/20
		1	34	12OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT IS LTF. CERTIFIED LETTER SENT 12/OCT/20
	C4591001 1133 11331472	1	33	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	Unable to contact subject
		1	33	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact subject
	C4591001 1133 11331481	1	24	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject doesn't feels comfortable receiving the second vaccine.
		1	24	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject does not feel comfortable receiving 2nd vaccine and withdrew consent from follow up as well
	C4591001 1134 11341130			20AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1135 11351019	2	29	22SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent during V3 on 22SEP2020
	C4591001 1140 11401002	2	12	28AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject no longer wanted to participate after experiencing a spontaneous coronary artery dissection
		2	32	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wanted to participate after experiencing a spontaneous coronary artery dissection

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1140 11401003	2	32	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Not interested in remaining in study
		2	32	17SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject not interested in continuing. Have been unable to reach to have come in for follow up
	C4591001 1140 11401035	1	50	22SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/URTICARIA
		1	50	22SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT
	C4591001 1142 11421111	1	19	04SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ABDOMINAL PAIN
		1	19	04SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/NIGHT SWEATS
	C4591001 1145 11451041	2	49	02NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	volunteer withdrawn no longer wants to be part of study.
		2	49	02NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	volunteer refuses to come for additional visits.
	C4591001 1145 11451076	1	18	21SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PARKINSONISM
	C4591001 1147 11471004	1	58	29SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Meets exclusion criterion 5
	C4591001 1149 11491105	2	61	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject is non responsive. Certified letter sent 30OCT2020.
		2	61	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is non responsive. Certified letter sent 30OCT2020.
	C4591001 1149 11491117	1	47	06OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent via phone call

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	47	06OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent via phone conversation.
	C4591001 1149 11491126	1	71	30OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject was mailed certified letter 30OCT2020.
		1	71	30OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Certified Letter sent 30OCT2020
	C4591001 1149 11491224	1	61	09NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject is non responsive. Certified letter sent 30OCT2020.
		1	61	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is non responsive. Certified letter sent 30OCT2020.
	C4591001 1152 11521359	1	8	11SEP2020	VACCINATION	ADVERSE EVENT	Subject does not want to receive second vaccination due to the AEs she had./MUSCLE SPASMS
	C4591001 1152 11521476	1	21	15OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DEAFNESS UNILATERAL
	C4591001 1152 11521497	1	31	06NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/SYNCOPE
	C4591001 1156 11561044	1	13	08SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	EXCLUSION CRITERIA #5
	C4591001 1157 11571028			17AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject could not make future study appointments
	C4591001 1157 11571131	1	23	24SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Voluntary withdrawal not due to an adverse event
		1	23	24SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Voluntary withdrawal not due to an AE or SAE

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1162 11621327	1	4	13SEP2020	VACCINATION	DEATH	Cause of Death Atherosclerotic Disease
		1	4	13SEP2020	FOLLOW-UP	DEATH	DEATH
	C4591001 1162 11621349	1	58	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU after many contact attempts
		1	58	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU after many contact attempts
	C4591001 1163 11631100	1	48	28SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject did not receive 2nd vaccination due to getting flu shot 6 days before V2 visit.
	C4591001 1168 11681012	2	29	01OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient withdrew consent
		2	29	01OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1168 11681015	1	21	02SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient withdrew consent
		1	21	02SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew consent
	C4591001 1170 11701354	1	29	16OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject contacted multiple times, never responded.
		1	29	16OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject contacted multiple times, never responded.
	C4591001 1174 11741041	2	35	03NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject withdrew from the trial before completing visit three for a personal reason
		2	35	03NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject has withdrawn from the study overall

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1178 11781056			31AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	subject randomized in error
	C4591001 1179 11791065	2	45	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	Despite repeated attempts to contact subject to scheduled V3 subject has not replied by final notice
		2	45	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Despite repeated attempts to contact subject to scheduled V3 subject has not replied by final notice
	C4591001 1185 11851006			27OCT2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	discontinued
	C4591001 1204 12041057	1	59	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew from the study.
		1	59	05NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew from the study.
	C4591001 1223 12231215			30SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject left after signing consent, before dosing and did not return.
	C4591001 1223 12231250			16OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject changed his mind.
	C4591001 1224 12241012	1	13	25AUG2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ANKLE FRACTURE
		1	13	25AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/FALL
		1	13	25AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/MUSCULAR WEAKNESS
		1	13	25AUG2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/TRANSIENT ISCHAEMIC ATTACK

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1224 12241033	2	37	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Dissatisfied with trial procedures.
	C4591001 1224 12241157			16SEP2020	FOLLOW-UP	PROTOCOL DEVIATION	PT is dialysis recipient; screen failure determined by study team during V1. PT discontinued
	C4591001 1226 12261613	1	22	28SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient chose not to take the second dose of the vaccine. Continue to the next visit
	C4591001 1229 12291041	1	35	02NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject is no longer interested in being part of the study.
		1	35	02NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject is no longer interested in being part of the study.
	C4591001 1231 12311154	2	35	07OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject in V3 at the moment of re-consenting decided not to.
		2	35	07OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not consent for amendment 6
	C4591001 1231 12311329	2	39	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdraws consent due to aggravation of chronic low back pain
		2	39	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdraws consent due to aggravation of chronic low back pain
	C4591001 1231 12311400	2	48	21OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer signed up to participate in another study.
		2	48	21OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The volunteer signed up to participate in another study.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12311549	1	37	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311709	1	37	22SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311723	1	23	08SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311810	2	31	07OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subjects affirms that the desition to stop participating in the study is personal
		2	31	07OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subjects affirms that the desition to stop participating in the study is personal
	C4591001 1231 12311935	1	22	08SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19.
	C4591001 1231 12312058	2	43	29OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to family reasons.
		2	43	29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to family reasons.
	C4591001 1231 12312130	1	38	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312222			19AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error
	C4591001 1231 12312530	2	19	28SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the volunteer refers that the decision to stop participating is due to personal reasons



### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		2	19	28SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the volunteer refers that the decision to stop participating is due to personal reasons
	C4591001 1231 12312571	1	28	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312855	2	26	04OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is for personal reasons
		2	26	04OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is for personal reasons
	C4591001 1231 12313003	1	20	09SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer states that the decision to stop participating in the study is of a personal nature.
		1	20	09SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The volunteer states that the decision to stop participating in the study is of a personal nature.
	C4591001 1231 12313039	1	29	19SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
		1	29	19SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject reports that the decision to stop participating in the study is of a personal nature
	C4591001 1231 12313090	1	46	06OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313103	1	31	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313457	1	33	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12313461	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject declined to receive second vaccination but wishes to continue in the study
	C4591001 1231 12313468	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject decides not to take the 2nd dose of the research product, and continues in follow-up
	C4591001 1231 12313478	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject explained that he didn't want to receive the second dose of investigation product
	C4591001 1231 12313480	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not want to receive a second dose but did continue in the study
	C4591001 1231 12313538	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time, but will continue in the study
	C4591001 1231 12313621	2	42	26OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
		2	42	26OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
	C4591001 1231 12313651	1	22	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313740	2	55	07NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject stops participating in the study due to emigration to another country.
		2	55	07NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject stops participating in the study due to emigration to another country.
	C4591001 1231 12313972	2	16	28SEP2020	VACCINATION	DEATH	DEATH

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		2	16	28SEP2020	FOLLOW-UP	DEATH	DEATH
	C4591001 1231 12314003	2	30	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
		2	30	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons
	C4591001 1231 12314060	1	57	20OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not reply to the registered letter. Contact is considered lost.
		1	57	20OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not reply to the registered letter. Contact is considered lost.
	C4591001 1231 12314120	1	20	14SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	did not agree that the Visit 1 swab result had not been given
		1	20	14SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	did not agree that the Visit 1 swab result had not been given
	C4591001 1231 12314189	1	20	14SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject misunderstood protocol and/or consent. Revokes consent.
		1	20	14SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	DISCONTINUED
	C4591001 1231 12314301	1	21	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12314863	1	28	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12315246	1	20	17SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12315608	1	20	19SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12315619	2	45	05NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
		2	45	05NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
	C4591001 1231 12315634	2	35	23OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
		2	35	23OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal reasons.
	C4591001 1231 12315672	1	22	21SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject in question decided to abandon the study for personal reasons.
		1	22	21SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject in question decided to abandon the study for personal reasons.
	C4591001 1232 12321105	1	64	28OCT2020	VACCINATION	LOST TO FOLLOW-UP	Unable to contact subject
		1	64	28OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact subject
	C4591001 1232 12321432			28OCT2020	FOLLOW-UP	PROTOCOL DEVIATION	Subject randomized in error
	C4591001 1247 12471066	1	43	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient tested positive for COVID 19 and was symptomatic prior to visit 2
	C4591001 1247 12471135	1	22	21OCT2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/CEREBRAL INFARCTION

## 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1248 12481026	1	23	20SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrew due to time commitment. Mother is very sick and she is taking care of her
		1	23	20SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew prior to 2nd vaccination.
	C4591001 1248 12481182			16SEP2020	FOLLOW-UP	OTHER	Randomized but not dosed.
	C4591001 1248 12481214	1	26	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject stated he no longers want to to continue with study per phone call
		1	26	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject no longer wishes to continue
	C4591001 1251 12511050	1	71	03NOV2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1251 12511236	1	23	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		1	23	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1254 12541074	2	38	28OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject requested to withdrawal consent
		2	38	28OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject wished to withdrawal consent.
	C4591001 1260 12601121	1	20	30SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient withdrew from study prior to vaccine # 2
		1	20	30SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrawal of consent

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1264 12641195	1	23	14OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Excl. 1 No further study intervention but will remain in the study to be evaluated for safety.
	C4591001 1269 12691124	2	1	29SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent
		2	1	29SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew consent
	C4591001 1270 12701057	1	61	02NOV2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/PULMONARY EMBOLISM
	C4591001 4444 44441152	1	22	12OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The volunteer expresses his desire to withdraw consent to participate in the study.
		1	22	12OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The volunteer expresses his desire to withdraw consent to participate in the study
	C4591001 4444 44441495	1	24	15OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	for personal causes
		1	24	15OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	for personal causes
	C4591001 4444 44441792	1	9	01OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject, re-reads consent and decided it is not what she'd understood. Decides to revoke consent.
		1	9	01OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject rejects the terms of consent on a subsequent rereading.
	C4591001 4444 44442179	1	2	28SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject reports being sure that he received placebo and that he participated to receive the vaccine.
		1	2	28SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject reports being sure that he received placebo and that he participated to receive the vaccine.

### 16.2.1.4 Listing of Subjects Withdrawn From the Study – All Subjects

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
-------------------	---------	----------	----------------------	-----------------	-------------	-------------------	----------------------

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: † = HIV-positive subject.

a. Relative Day (Rel Day) = date of withdrawal - date of last vaccination + 1. For a withdrawal that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. MedDRA (v23.1) coding dictionary applied.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 19NOV2020 (01:42)

(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2\_unblinded/C4591001\_IA\_P3\_2MPD2/adds\_1001\_withdraw\_p3

### 16.2.1.6 Listing of Subjects Withdrawn From the Study – Subjects Enrolled in Multiple Sites

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
16-55	C4591001 1056 10561101	2	44	03NOV2020	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT WAS FOUND AS A DUPLICATE FROM ANOTHER SITE IN CLOSE PROXIMITY.

a. Relative Day (Rel Day) = date of withdrawal - date of last vaccination + 1. For a withdrawal that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. MedDRA (v23.1) coding dictionary applied.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adds Table Generation: 18NOV2020 (02:59)  
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2\_unblinded/C4591001 IA P3 2MPD2/adds 1001 wd menrol p3