

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/27/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10091123]
2.	Birth Date:	(b) (6) 1947
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Aug/27/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Form Comments](#)

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable _____
----	---	-------------------------

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable _____
----	---	-------------------------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/27/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastroesophageal Reflux Disease]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/1987
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	Jun/UNK/2020
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypercholesterolemia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Posterior Septal Resection]
	Start Date:	UNK/UNK/2017
	Ongoing:	NO End Date: UNK/UNK/2017
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hysterectomy]
	Start Date:	UNK/UNK/2019
	Ongoing:	NO End Date: UNK/UNK/2019
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Abnormal discharge uterine cervix]
	Start Date:	UNK/UNK/2019
	Ongoing:	NO End Date: UNK/UNK/2019

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Post Menopausal]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Partial Thyroidectomy]
	Start Date:	UNK/UNK/1975
	Ongoing:	NO End Date: UNK/UNK/1975
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Benign Thyroid Nodule]
	Start Date:	UNK/UNK/1975
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

1 m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ascending colon polyp]
	Start Date:	Mar/UNK/2020
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/27/2020
2.	Weight:	[166.0]
3.	Unit:	LB
4.	Height:	[63.0]
5.	Unit:	in
6.	Body Mass Index:	[29.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[99.0]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Form Comments](#)
[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Applicable _____ //	Comments
4.	Laboratory Name and Address (Derived)	[]	
5.	Specimen Type:		

Lab Result

6.a	Sponsor ID:	[113]	Comments
	Test:	Choriogonadotropin Beta_PX113	
	Result:		Comments
	Not Done:	NOT DONE	Comments

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/27/2020
2.	Randomization Number:	[243682]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9GJ8]
5.b	Sample ID	[BP9GJ9]
5.c	Sample ID	[BP9GJB]
5.d	Sample ID	[BPR976]
5.e	Sample ID	[BPR977]

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9G1L]
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090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/27/2020 14:09
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/15/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/15/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9G6H]
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090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/15/2020 11:15
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/13/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/13/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BM85Y4]
5.b	Sample ID	[BM85Y5]
5.c	Sample ID	[BM85Y6]
5.d	Sample ID	[BRTSK2]
5.e	Sample ID	[BPR99C]

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BSJ4GV]
5.b	Sample ID	[BSJ420]
5.c	Sample ID	[BTWNXY]

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123 **Subject Initials:** ---

Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
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090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 Visit

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Signs and Symptoms

1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

5.	Symptoms - Other Text:	[]
----	------------------------	-----

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[]
----	-------------------------------------	-----

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
----	--	--

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	
----	-------------------------	--

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Unplanned Assessments

1.	Assessments	
----	-------------	--

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisc

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/13/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New **Form:** DATE OF VISIT - REPEAT SWAB
Unscheduled Visit

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	TUBULAR ADENOMA OF ASCENDING COLON	Jun/UNK/2020 UNK:UNK	NO End Date Time: Dec/17/2020 UNK: UNK	Repeating Pages

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[TUBULAR ADENOMA OF ASCENDING COLON]
4.	Start Date Time:	Jun/UNK/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/17/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [NEW GROWTH]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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Medication Error

1.	Category:	
2.	Medication Error (Type of Medication Error):	[]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	SHINGRIX #1	Oct/17/2020	Repeating Pages
2.	2	VACCINATIONS	NO	SHINGRIX #2	Jan/12/2021	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[SHINGRIX #1]
5.	Date:	Oct/17/2020

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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Concomitant Medications

1.	What is the medication identifier?	[2]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[SHINGRIX #2]
5.	Date:	Jan/12/2021

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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Concomitant Medications

1.	What is the medication identifier?	[]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[]
5.	Dose:	[]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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Radiation Treatment

1.	Category:	
2.	What is the treatment Identifier?	[]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Vital Signs

1.	Date:	//
----	-------	----

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[]
	Test:	
	Result:	
	Not Done:	

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Vaccination

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Contact Outcome

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form Version: 14-Jan-2021 02:29

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: INFORMED CONSENT - ASYMPTOMATIC
SURVEILLANCE

Form Status: Not Started

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
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Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Electronic Sample Tracking

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
----	-----------	-----

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/12/2021
2.	Erroneous Visit	

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2
----	---	--

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisc

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/12/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//
----	------------------------------	----

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Death Details

1.	Date of Collection / Notification of Death:	//
----	---	----

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisc

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/13/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisc

Generated Time (GMT): 29-Mar-2021 04:12

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
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090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
------	-------------------	------	------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-27-2020 17:38:26 (UTC-07:00) Mountain Time (US & Canada)	Mikaela Jones (pfe.mjones)	Not Applicable

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-28-2020 07:38:35 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	na

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
3	Aug-28-2020 07:38:48 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-28-2020 07:39:31 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	na
6.a	Aug-28-2020 07:38:58 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	na

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-28-2020 07:39:31 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	na
6.a	Aug-28-2020 07:38:58 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	na

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-28-2020 07:39:31 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	na
6.a	Aug-28-2020 07:38:58 (UTC-07:00) Mountain Time (US & Canada)	Dylan Owen (pfe.dowen)	na

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Colby Bostock	N/A	Mar-11-2021 12:07:17 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Shane Christensen	Approved	Mar-06-2021 16:56:48 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, ShaneChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
Allyson Christensen	N/A	Feb-24-2021 10:26:07 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Shane Christensen	Approved	Oct-23-2020 13:59:09 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Affidavit:

By my dated signature below, I, ShaneChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-27-2020 17:29:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-27-2020 17:29:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Consent Was:

Date	Location	User	Value	Reason
Aug-27-2020 17:38:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtained Aug/27/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Subject ID

Date	Location	User	Value	Reason
Aug-27-2020 17:29:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10091123	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-27-2020 17:29:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1947	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-27-2020 17:38:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-27-2020 17:38:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-27-2020 17:38:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: WHITE	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Aug-27-2020 17:38:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Aug/27/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-27-2020 17:38:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Aug/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-27-2020 17:38:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-27-2020 17:38:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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I.a

Date	Location	User	Value	Reason
Aug-27-2020 17:39:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Gastroesophageal Reflux Disease Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 17:39:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

I.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-27-2020 17:39:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Gastroesophageal Reflux Disease	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 17:39:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: UNK/UNK/1990	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 17:39:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones	Data Entry: YES	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Time (US & Canada)

(pfe.mjones)

I.b

Date	Location	User	Value	Reason
Aug-27-2020 17:39:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: Depression Start Date: UNK/UNK/ 1987 Ongoing: YES	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 17:39:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-27-2020 17:39:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Depression	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 17:39:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: UNK/UNK/1987	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 17:39:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-27-2020 17:39:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3 : Medical History T Hypertensio erm: n Start Date: Jun/UNK/2 020 Ongoing: YES	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 17:39:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-27-2020 17:39:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Hypertension	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 17:39:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Jun/UNK/2020	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 17:39:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-27-2020 17:40:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History: Osteoarthritis Term: s Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 17:40:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-27-2020 17:40:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Osteoarthritis	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 17:40:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: UNK/UNK/2018	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 17:40:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-27-2020 17:40:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Hypercholesterolemia Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 17:40:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-27-2020 17:40:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Hypercholesterolemia	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 17:40:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: UNK/UNK/2010	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 17:40:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-27-2020 17:41:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Line/MH Number: 6 Medical History Term: Posterior Septal Resection Start Date: UNK/UNK/2017	Transcription Error

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

			Ongoing: NO End Date: UNK/UNK/ 2017	
Aug-27-2020 17:40:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 6 mber: Medical Hist Posterior Septa ory Term: l Resection Start Date: UNK/UNK/20 17 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 10091123

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

I.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 17:40:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

I.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-27-2020 17:40:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Posterior Septal Resection	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 17:40:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: UNK/UNK/2017	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 17:41:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe mjones)	Data Entry: NO End Date: UNK/UNK/2017	Transcription Error
Aug-27-2020 17:40:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe mjones)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-27-2020 17:41:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7	Initial Entry

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Header Text: c4591001

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Subject No: 10091123

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Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

			Medical History Hysterectomy Term: Start Date: UNK/UNK/2019 Ongoing: NO End Date: UNK/UNK/2019	
--	--	--	---	--

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 17:41:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-27-2020 17:41:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Hysterectomy	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 17:41:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: UNK/UNK/2019	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 17:41:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: NO End Date: UNK/UNK/2019	Initial Entry

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Header Text: c4591001

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Subject No: 10091123

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l.h

Date	Location	User	Value	Reason
Sep-04-2020 19:18:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: Line/MH Number: 8 Medical History Term: Abnormal discharge uterine cervix Start Date: UNK/UNK/2019 Ongoing: NO End Date: UNK/UNK/2019	Transcription Error
Aug-31-2020 14:30:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: Line/MH Number: 8 Medical History Term: Abnormal Uterine Discharge Start Date: UNK/UNK/2019 Ongoing: NO End Date: UNK/UNK/2019	Transcription Error
Aug-27-2020 17:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: Abnormal Uterine Discharge Start Date: UNK/UNK/2019 Ongoing: NO End Date: UNK/UNK/2019	Initial Entry

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Header Text: c4591001

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Subject No: 10091123

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Subject Initials: ---

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1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-05-2020 10:00:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 4: Closed	Discrepancy has been closed.
Sep-04-2020 19:18:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Transcription Error
Sep-04-2020 19:18:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: Abnormal discharge uterine cervix	Transcription Error
Sep-04-2020 10:30:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 4: Reissued: Opened	Coding cannot take place with the term as is. Please update to further specify the term. Are you reporting ABNORMAL

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Header Text: c4591001

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Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

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				DISCHARGE UTERINE CERVIX? UTERINE BLEEDING? If so, update the verbatim term as such. Otherwise clarify and edit the term.
Sep-02-2020 13:40:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 4: Ans wered	correct as is. this discharge was unknown and no further diagnosis
Sep-01-2020 01:49:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 2: Clo sed	Response satisfies query
Aug-31-2020 20:43:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 4: Ope ned	Clarify ABNORMAL UTERINE DISCHARGE as follows...Are you reporting ABNORMAL DISCHARGE UTERINE CERVIX? UTERINE BLEEDING? If so, update the verbatim term as such. Otherwise clarify and edit the term.

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Header Text: c4591001

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Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

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				Thank you.
Aug-31-2020 20:40:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Clo sed	Discrepancy has been closed.
Aug-31-2020 20:15:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 3: Ope ned	Clarify ABNORMAL UTERINE DISCHARGE as follows...Are you reporting ABNORMAL DISCHARGE UTERINE CERVIX? UTERINE BLEEDING? If so, update the verbatim term as such. Otherwise clarify and edit the term. Thank you.

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Subject No: 10091123

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Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

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1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-31-2020 18:54:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Clo sed	Discrepancy has been closed.
Aug-31-2020 14:30:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: An swere d	Transcription Error
Aug-31-2020 14:30:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry : Abnor mal U terine Disch arge	Transcription Error
Aug-31-2020 10:58:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Swaranjali Subhash Pawar (pfe.pawars01)	Query 2: Op ened	DM: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).

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Header Text: c4591001

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Site No: 1009

Subject No: 10091123

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

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Aug-31-2020 09:11:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: An swere d	the discharge was unknown, not bleeding and no diagnosis associated.
Aug-31-2020 06:07:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jeffrey Signora TMSQUERY (pfe.signoj01_tmsquery)	Query 1: Rei ssued: Open ed	Coding cannot take place as is. Are you reporting ABNORMAL DISCHARGE UTERINE CERVIX? UTERINE BLEEDING? If so, update the verbatim term as such. Otherwise clarify and edit the term.
Aug-28-2020 07:38:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: An swere d	no further clarification, not ongoing, hysterectomy
Aug-28-2020 06:58:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Op ened	Clarify ABNORMAL UTERINE DISCHARGE as follows...Are you reporting ABNORMAL DISCHARGE UTERINE CERVIX? UTERINE

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Subject Initials: ---

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				BLEEDING? If so, update the verbatim term as such. Otherwise clarify and edit the term. Thank you.
Aug-27-2020 17:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry : Abnormal Uterine Discharge	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe mjones)	Data Entry: UNK/UNK/2019	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe mjones)	Data Entry: NO End Date: UNK/UNK/2019	Initial Entry

I.i

Date	Location	User	Value	Reason
Aug-27-2020 19:47:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: r:	Initial Entry

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Header Text: c4591001

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Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

			Medical History Term: Post Menopausal Start Date: UNK/UNK/1998 Ongoing: YES
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1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 19:47:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-27-2020 19:47:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Post Menopausal	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 19:47:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: UNK/UNK/1998	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 19:47:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Sep-16-2020 21:23:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 10	Initial Entry

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Header Text: c4591001

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Subject No: 10091123

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

			r: Medical History Insomnia Term: Start Date: UNK/UNK/ 2015 Ongoing: YES	
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1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 21:23:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-16-2020 21:23:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Insomnia	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 21:23:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: UNK/UNK/2015	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 21:23:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: YES	Initial Entry

1.k

Date	Location	User	Value	Reason
Sep-21-2020 12:46:13	ACV0PFEINFP6000	Dylan	Data Entry:	Transcription Error

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

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Site No: 1009

Subject No: 10091123

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Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

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(UTC-07:00) Mountain Time (US & Canada)		Owen (pfe.dowen)	Line/MH Number: 11 Medical History Term: Partial Thyroidectomy Start Date: UNK/UNK/1975 Ongoing: NO End Date: UNK/UNK/1975	
Sep-16-2020 21:23:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: Partial Thyroidectomy Start Date: UNK/UNK/1975 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Subject No: 10091123

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Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

1.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 21:23:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-16-2020 21:23:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Partial Thyroidectomy	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 21:23:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: UNK/UNK/1975	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 18:21:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Closed	Response satisfies query
Sep-21-2020 12:46:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-21-2020 12:46:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: NO End Date: UNK/UNK/1975	Transcription Error
Sep-20-2020 23:20:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Opened	ClinQuery: Partial Thyroidectomy: As this is a procedure, please can you

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

				provide a stop date
Sep-20-2020 18:22:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Xiaoxia Liu (pfe.xiaoxl)	Query 1: Candidate	ClinQuery: Partial Thyroidectomy: As this is a procedure, please can you provide a stop date
Sep-16-2020 21:23:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: YES	Initial Entry

1.1

Date	Location	User	Value	Reason
Sep-16-2020 21:23:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: Benign Thyroid Nodule Start Date: UNK/UNK/1975 Ongoing: YES	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 21:23:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-16-2020 21:23:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Benign Thyroid Nodule	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 21:23:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: UNK/UNK/1975	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 21:23:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Oct-19-2020 21:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 Medical History Term: ascending colon polyp Start Date: Mar/UNK/2020 Ongoing: YES	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

I.m Line/MH Number:

Date	Location	User	Value	Reason
Oct-19-2020 21:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

I.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Oct-19-2020 21:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: ascending colon polyp	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 21:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: Mar/UNK/2020	Initial Entry

I.m Ongoing:

Date	Location	User	Value	Reason
Oct-19-2020 21:35:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: YES	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Aug/27/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: 166.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: 63.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
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090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1009**Subject No:** 10091123**Generated By:** pfe.levisse**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Aug-27-2020 17:42:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 29.4	Initial Entry
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7.a

Date	Location	User	Value	Reason
Aug-27-2020 17:42:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Record Identifier 1 :: Temperature: 99.0 Temperature Uni F t: Temperature Loc ORAL CA ation:: VITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: 99.0	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Aug-27-2020 17:42:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: ORAL CAVITY	Initial Entry
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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091123**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-28-2020 07:38:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-27-2020 17:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier 113 : Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-27-2020 17:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Aug-27-2020 17:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: NOT DONE	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-27-2020 17:43:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Aug/27/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-27-2020 17:43:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: 243682	Initial Entry

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Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic
South**Subject No:** 10091123**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-27-2020 17:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-27-2020 17:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-27-2020 17:44:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 17:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-27-2020 17:43:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: YES Date of Collection: Aug/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 17:44:54	ACV0PFEINFP6000	Mikaela	Data Entry:	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1009
Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South
Subject No: 10091123
Subject Initials: ---
Generated By: pfe.levisse
Generated Time (GMT): 29-Mar-2021 04:12

(UTC-07:00) Mountain Time (US & Canada)		Jones (pfe.mjones)	Sample ID: BP9GJ8	
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 17:44:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: BP9GJ8	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-27-2020 17:45:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Sample ID: BP9GJ9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 17:45:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: BP9GJ9	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-27-2020 17:45:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Sample ID: BP9GJB	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 17:45:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: BP9GJB	Initial Entry

5.d

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Aug-27-2020 17:45:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Sample ID: BPR976	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 17:45:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: BPR976	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-27-2020 17:45:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Sample ID: BPR977	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 17:45:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: BPR977	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091123**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-27-2020 17:43:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-27-2020 17:43:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-27-2020 17:45:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 17:43:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-27-2020 17:43:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: YES Date of Collection: Aug/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 17:45:36	ACV0PFEINFP6000	Mikaela	Data Entry:	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1009
Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South
Subject No: 10091123
Subject Initials: ---
Generated By: pfe.levisse
Generated Time (GMT): 29-Mar-2021 04:12

(UTC-07:00) Mountain Time (US & Canada)		Jones (pfe.mjones)	Sample ID: BP9G1L	
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5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 17:45:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: BP9G1L	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:04**Site No:** 1009**Subject No:** 10091123**Generated By:** pfe.levisse**Form:** VACCINATION - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-27-2020 17:43:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-27-2020 17:43:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-27-2020 17:43:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-27-2020 17:43:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Aug/27/2020 14:09	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-27-2020 17:43:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Aug-27-2020 17:43:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Aug-27-2020 17:43:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-27-2020 17:43:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-27-2020 17:43:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: YES	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-27-2020 17:43:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: NO - REACTOGENICITY E-D IARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-16-2020 12:29:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Sep/15/2020	Initial Entry

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 15-Sep-2020 21:54**Site No:** 1009**Subject No:** 10091123**Generated By:** pfe.levisse**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Sep-16-2020 12:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Sep/15/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-16-2020 12:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Record Identifier 1 :: Temperature: 98.1 Temperature Unit: Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 12:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-16-2020 12:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: 98.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Sep-16-2020 12:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: F	Initial Entry
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2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-16-2020 12:30:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091123**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-16-2020 12:31:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-16-2020 12:31:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-16-2020 12:31:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Sep/15/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-16-2020 12:31:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-16-2020 12:31:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Sep-16-2020 12:31:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier 113 : Test:: Choriogonadotropin Beta_PX113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-16-2020 12:31:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-16-2020 12:31:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Sep-16-2020 12:31:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: NOT DONE	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 12:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 12:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 12:31:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe mjones)	Data Entry: YES Date of Collection: Sep/15/2020	Transcription Error
Sep-16-2020 12:31:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 12:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 12:31:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe mjones)	Data Entry: YES	Initial Entry

5.a

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Sep-16-2020 12:31:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Sample ID: BP9G6H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 12:31:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: BP9G6H	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-16-2020 12:32:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-16-2020 12:32:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-16-2020 12:32:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-16-2020 12:32:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: Sep/15/2020 11:15	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 12:32:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
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090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Sep-16-2020 12:32:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: LEFT	Initial Entry
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7. Route:

Date	Location	User	Value	Reason
Sep-16-2020 12:32:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-16-2020 12:32:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-16-2020 12:32:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: YES	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 12:08:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Oct/13/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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1. Data Origin

Date	Location	User	Value	Reason
Oct-13-2020 12:09:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-13-2020 12:09:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-13-2020 12:09:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 12:09:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-13-2020 12:09:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES Date of Collection: Oct/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-13-2020 12:09:22	ACV0PFEINFP6000	Annjanette	Data Entry:	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1009 **Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South
Subject No: 10091123 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:12

(UTC-07:00) Mountain Time (US & Canada)		Kemp (pfe.akemp)	Sample ID: BM85Y4	
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5.a Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 12:09:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: BM85Y4	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-13-2020 12:09:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sample ID: BM85Y5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 12:09:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: BM85Y5	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-13-2020 12:09:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sample ID: BM85Y6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 12:09:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: BM85Y6	Initial Entry

5.d

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Oct-13-2020 12:10:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sample ID: BRTSK2	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 12:10:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: BRTSK2	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-13-2020 12:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sample ID: BPR99C	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 12:10:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: BPR99C	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 12:08:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Mar/11/2021	Initial Entry

Header Text: c4591001**Visit:** V4_MONTH6_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic
South**Subject No:** 10091123**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-11-2021 12:07:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-11-2021 12:07:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-11-2021 12:07:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 12:07:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-11-2021 12:07:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: YES Date of Collection: Mar/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
- eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Mar-11-2021 12:07:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Sample ID: BSJ4GV	Initial Entry
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5.a Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 12:07:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: BSJ4GV	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-11-2021 12:07:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Sample ID: BSJ420	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 12:07:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: BSJ420	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-11-2021 12:07:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Sample ID: BTWNXY	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 12:07:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: BTWNXY	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-13-2020 12:10:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Oct/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-13-2020 12:10:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-13-2020 12:10:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Category:

Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: TUBULAR ADENOMA OF ASCENDING COLON	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-12-2021 16:23:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Query 1: Answered	correct as is, sae, no changes at this time to be made
Mar-12-2021 14:52:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Query 2: Answered	awaiting unlocking of medical history to add it there. It was also capture on AE because subject was hospitalized during the removal, this met SAE criteria
Mar-12-2021 02:27:03	ACV0PFEINFP6000	Malerato	Query 2: Reissued:Opened	DM: Thanks for the

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

(UTC-07:00) Mountain Time (US & Canada)		Moloi (pfe.moloim)		response. Please clarify if TUBULAR ADENOMA OF ASCENDING COLON should be an AE or part of patients medical history since it started before VID1VX1L visit date. If yes, please review and update the data as appropriate. Else, clarify.
Mar-12-2021 00:32:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Reissued:Opened	DM: If event occurred before vaccination, please delete from here and update as a Medical History.
Mar-11-2021 17:46:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Query 2: Answered	CORRECT AS IS
Mar-11-2021 17:46:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Query 1: Answered	CORRECT AS IS
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For TUBULAR ADENOMA OF ASCENDING COLON: Start date UNK/Jun/2020 is before VID1VX1L visit date 27/Aug /2020. Please review and update as appropriate.
Mar-11-2021 17:45:34 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start date is before Consent Date

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

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Time (US & Canada)				27/Aug/2020.
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Jun/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NO End Date Time: Dec/17/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE TUBULAR ADENOMA OF ASCENDING COLON: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Mar-11-2021 17:45:34	ACV0PFEINFP6000	Annjanette	Data Entry:	Initial Entry

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091123**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Answered Queries**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12(UTC-07:00) Mountain
Time (US & Canada)Kemp
(pfe.akemp)

YES

Is this serious event associated with congenital anomaly or birth defect?

NO

Did this serious event result in death?

NO

Did this serious event require or prolong hospitalization?

YES

Did this serious event result in persistent or significant disability/incapacity?

NO

Is this serious event life threatening?

NO

Other medically important serious event

NO

8. Is this adverse event the result of a study Medication Error?*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> NEW GROWTH	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-12-2021 14:50:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Query 1: Answered	if there were any prohibited medications they would be captured on the prohibited medications page
Mar-12-2021 10:49:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: the answer to: Was a Concomitant Medication given? is YES. Please clarify which medications and if a prohibited systemic immunosuppressive therapy was given, please also update PROHIB_CM page. Else, please clarify.

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091123

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

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Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry
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12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-11-2021 17:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Mar-11-2021 17:47:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
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Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

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Date	Location	User	Value	Reason
Mar-11-2021 17:47:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Mar-11-2021 17:47:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Mar-11-2021 17:47:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Mar-11-2021 17:47:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Mar-12-2021 16:59:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Cl osed	Discrepancy has been closed.
Mar-12-2021 14:17:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: A nswered	Transcription Error

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

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Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

Mar-12-2021 14:17:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.down)	Data Entry: SHINGRIX #1	Transcription Error
Mar-12-2021 01:00:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: O pened	Clarify SHINGREX #1 as follows...Should the spelling be SHINGRIX #1? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you.
Mar-11-2021 17:47:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: SHINGRE X #1	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Mar-11-2021 17:47:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Oct/17/2020	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
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Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Mar-11-2021 17:47:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Mar-11-2021 17:47:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Mar-11-2021 17:47:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Mar-12-2021 17:00:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Cl osed	Discrepancy has been closed.
Mar-12-2021 14:18:26 (UTC-07:00) Mountain Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: A nswered	Transcription Error

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
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Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

(US & Canada)				
Mar-12-2021 14:18:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: SHINGRI X #2	Transcription Error
Mar-12-2021 01:01:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: O pened	Clarify SHINGREX #2 as follows...Should the spelling be SHINGRIX #2? If so, update the verbatim term as such. Otherwise clarify and update the term as appropriate or provide reference/label. Thank you.
Mar-11-2021 17:47:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: SHINGRE X #2	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Mar-11-2021 17:47:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Jan/12/2021	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-24-2021 10:26:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Allyson Christensen (pfe.achristensen)	Data Entry: Jan/12/2021	Initial Entry

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Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic
South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 04:12

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-24-2021 10:26:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-24-2021 10:26:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-24-2021 10:26:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Allyson Christensen (pfe.achristensen)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.lewissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-24-2021 10:26:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Allyson Christensen (pfe.achristensen)	Data Entry: Jan/12/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-24-2021 10:26:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Allyson Christensen (pfe.achristensen)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATI ON	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091123

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:12

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1. Subject Status

Date	Location	User	Value	Reason
Oct-13-2020 12:10:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-27-2020 17:43:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-27-2020 17:38:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-13-2020 12:10:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/13/2020	Initial Entry
Aug-27-2020 17:43:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/27/2020	Initial Entry
Aug-27-2020 17:38:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/27/2020	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1009

Site Name: (1009) J. Lewis Research, Inc. Foothill Family Clinic South

Subject No: 10091123

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:12

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 11:17:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3fa3\Final\Final On: 01-Apr-2021 05:20 (GMT)