

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[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: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/24/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10061094]
2.	Birth Date:	(b) (6)/1985
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:	

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Aug/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

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
----	--	----------------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation/Death	Aug/24/2020
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: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MIGRAINES]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MUSCLE SPASMS (BACK AND SHOULDERS)]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MILD ASTHMA]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SEASONAL ALLERGIES]
	Start Date:	UNK/UNK/1988
	Ongoing:	YES

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OPSTURAL ORTHOSTATIC TACHYCHARDIA SYNDROME]
	Start Date:	UNK/UNK/1986
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[EHLRS DAULOS SYNDROME]
	Start Date:	UNK/UNK/1986
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[POST TRAUMATIC STRESS DISORDER]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DIFFUSE SPASTIC ESOPHAGUS]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ORAL COLD SORES]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ATTENTION DEFICIT DISORDER]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[TEMPORPMANDIBULAR JOINT DYSFUNCTION]
	Start Date:	UNK/UNK/2003
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[NISSEN FUNDIPLICATION]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GASTROESOPHAGEAL REFLUX DISEASE]
	Start Date:	UNK/UNK/1986
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DEVIATED SEPTUM]
	Start Date:	UNK/UNK/1987
	Ongoing:	NO End Date: UNK/UNK/2004

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HEART MURMUR]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DEVIATED SEPTUM REPAIR]
	Start Date:	UNK/UNK/2004
	Ongoing:	NO End Date: UNK/UNK/2004
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ACNE (FACIAL)]
	Start Date:	UNK/UNK/1998
	Ongoing:	YES
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[AMOXICILLIN ALLERGY]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[IODINATED CONTRAST MEDIA ALLERGY]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[PENICILLIN G ALLERGY]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RECURRENT SINUSITIS]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/24/2020
2.	Weight:	[137.6]
3.	Unit:	LB
4.	Height:	[69.0]
5.	Unit:	in
6.	Body Mass Index:	[20.3]

Vital Signs Details

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

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061094

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/24/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/24/2020
2.	Randomization Number:	[61617]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
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	[BHV2Y9]
5.b	Sample ID	[BHV2YB]
5.c	Sample ID	[BHV2YC]
5.d	Sample ID	[BJ7LY9]
5.e	Sample ID	[BJ7LYB]

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
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	[BHV2PV]
-----	-----------	----------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[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/24/2020 09:46
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

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
----	--	---

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Sep/18/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/18/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061094

Generated By: pfe.lewissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/18/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

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

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[SAMPLE CAPTURED IN COVID ILLNESS VISIT A]

Aliquot

Please enter barcode for each aliquot.

5-a	Sample ID	[BH2422]
-----	-----------	----------

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

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/18/2020 13:29
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

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/16/2020
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	[BCT8DR]
5.b	Sample ID	[BJ7M85]
5.c	Sample ID	[BJ7MF6]

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.lewissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/12/2021
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	[BRBMG0]
5.b	Sample ID	[BS8WM8]
5.c	Sample ID	[BS8WPN]

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

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: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

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	[]
----	-----------	-----

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

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: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

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	[]
----	-----------	-----

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Sep/18/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/18/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Sep/18/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Sep/18/2020
2.	Date of First Symptom Started:	Sep/10/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Sep/15/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Sep/18/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

4.i	Symptoms:	VOMITING
	Was symptom present?	NO
Symptoms - Other		
5.a	Symptoms - Other Text:	[NASAL CONGESTION]
5.b	Symptoms - Other Text:	[NASAL DISCHARGE DISCOLORATION]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Done	Not Done	Not Done	Not Done	Not Done	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

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

Microbiology Specimen

1.	Actual Date of Collection:	Not Done _____ //	Comments
2.	Specimen Type:	Not Done _____	Comments
3.	Specimen Collection Location:	Not Done _____	Comments
4.	Assay Code and Description:	Not Done _____	Comments
5.	Device Type:	Not Done _____	Comments
6.	Trade Name:	Not Done _____	Comments
7.	Test Result:	Not Done _____	Comments
8.	Comments/Findings/Details:	Not Done _____ []	Comments
9.	Trade Name Other, Specify:	Not Done _____ []	Comments

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Sep/18/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[SWAB PFE COLLECTED AT VISIT 2]

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB on Sep/18/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/18/2020
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	[BH2422]
-----	-----------	----------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Sep/18/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

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?	NO
----	--	----

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Sep/18/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Sep/18/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [UPPER RESPIRATORY TRACT INFECTION] Date of Diagnosis: Sep/18/2020
3.	Toxicity Grade:	2

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Sep/18/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Illness Details

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Sep/18/2020

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Lab Chemistry Details

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	Repeating Pages

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/18/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[]
	Test:	
	Result:	[]
	Not Done:	
	LNMT	Low [] High [] Unit

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lewissc

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

#	Date:	Vital Signs Details			Form Instance
1.		Record Identifier:	Systolic:	Diastolic:	Repeating Pages

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Sep/18/2020

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[]
	Diastolic:	[]
	Respiratory Rate in respirations/minute:	[]
	Heart Rate in beats/minute:	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lewissc

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

#	Date:	Vital Signs Details		Form Instance
1.		Record Identifier:	Oxygen Saturation	Repeating Pages

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Sep/18/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lewissc

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Sep/18/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Oxygenation Parameters

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[]
3.	FiO2 (Fraction of Inhaled Oxygen):	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Sep/18/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

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.	Start Date:	//
6.	Ongoing?	

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lewissc

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Sep/18/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Imaging

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Oct/22/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/22/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Oct/22/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/22/2020
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	[BH2442]
5.b	Sample ID	[BSJPKD]
5.c	Sample ID	[BJ7MG7]

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lewissc

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation/Death :	Oct/16/2020
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: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

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
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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	[]
----	-----------	-----

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1. DELETED	ADVERSE EVENT	1	Upper Respiratory Tract Infection	Sep/10/2020 UNK:UNK	NO End Date Time: Sep/15/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	INJECTION SITE PAIN	Sep/19/2020 18:00	NO End Date Time: Sep/20/2020 18:00	Repeating Pages
3.	ADVERSE EVENT	3	FEVER	Sep/19/2020 18:00	NO End Date Time: Sep/20/2020 18:00	Repeating Pages
4.	ADVERSE EVENT	4	GENERALIZED ACHES	Sep/19/2020 18:00	NO End Date Time: Sep/20/2020 18:00	Repeating Pages
5.	ADVERSE EVENT	5	Exposure During Pregnancy	Nov/15/2020 UNK:UNK	YES	Repeating Pages

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[+]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Upper Respiratory Tract Infection]
4.	Start Date Time:	Sep/10/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/15/2020 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).	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.	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: [URI VIRAL]

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

***** THIS REPEATING FORM HAS BEEN DELETED *****

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	[]

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[INJECTION SITE PAIN]
4.	Start Date Time:	Sep/19/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/20/2020 18:00
6.	Toxicity Grade:	1
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).	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.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
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	[]

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[FEVER]
4.	Start Date Time:	Sep/19/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/20/2020 18:00
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).	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.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
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	[]

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[GENERALIZED ACHES]
4.	Start Date Time:	Sep/19/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/20/2020 18:00
6.	Toxicity Grade:	1
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).	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.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
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	[]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[5]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure During Pregnancy]	
4.	Start Date Time:	Nov/15/2020 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments
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).	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.	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: [condom failure]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[]

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

#	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: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

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	[]

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

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.	Date:	//

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

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?	

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

Vital Signs

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

Vital Signs Details

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

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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:	

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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?	

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

Informed Consent - Asymptomatic Surveillance

1.	Consent Was:	
----	--------------	--

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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	[]
----	-----------	-----

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

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	[]
----	-----------	-----

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

eCRF Audit Trail History

Date of Visit

1.	Date of Visit	Feb/2/2021
2.	Erroneous Visit	

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[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: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/5/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.lewissc

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

Withdrawal Of Consent

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

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.lewissc

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

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: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/16/2020

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Casebook Signature Form

1.	Casebook Signature	Click Here to Enable
----	--------------------	----------------------

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[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: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-25-2020 14:47:45 (UTC-07:00) Mountain Time (US & Canada)	Maddie Grote (pfe.mgrote)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
Form	Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
1	Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
2	Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
3	Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
4	Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
5	Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
6	Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
7	Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
8	Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Item	Date	User	Comment
9	Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Deleted

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6	Dec-03-2020 13:42:22 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[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
Bradley Young	N/A	Mar-12-2021 11:07:51 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated

Affidavit:

N/A

James Peterson	Approved	Mar-08-2021 15:49:52 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
----------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, JamesPeterson, 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.

Lindsey Bevan	N/A	Feb-05-2021 14:01:58 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
---------------	-----	--	--	-----------------------------------

Affidavit:

N/A

James Peterson	Approved	Jan-22-2021 19:10:36 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
----------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, JamesPeterson, 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.

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Lindsey Bevan	N/A	Dec-03-2020 13:41:52 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
---------------	-----	--	--	-----------------------------------

Affidavit:

N/A

James Peterson	Approved	Dec-01-2020 17:44:54 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
----------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, JamesPeterson, 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.

Bradley Young	N/A	Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
---------------	-----	--	--	-----------------------------------

Affidavit:

N/A

James Peterson	Approved	Oct-29-2020 14:11:08 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
----------------	----------	--	------	--------

Affidavit:

By my dated signature below, I, JamesPeterson, 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.

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lewissc

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-25-2020 14:46:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 14:46:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Aug-25-2020 14:47:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: OBTAINED Date Written Consent Obtained Aug/24/2020	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1006

Subject No: 10061094

Generated By: pfe.lewissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Subject ID

Date	Location	User	Value	Reason
Aug-25-2020 14:46:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10061094	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:46:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1985	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-25-2020 14:47:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-25-2020 14:47:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	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-25-2020 14:47:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: WHITE	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Sep-30-2020 04:26:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Per site confirmation
Sep-29-2020 04:18:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Reissued:Candidate	Added to DM Ops tracker. Kindly review the Ops tracker and take appropriate action.
Sep-28-2020 11:47:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Deemed not related to COVID per investigator
Sep-28-2020 11:19:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonali shah (pfe.shahs132)	Query 1: Opened	As per Illness ediary records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 31AUG2020. But there is no COVID Illness visit reported in the database. Please clarify.
Aug-25-2020 14:47:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe.mgrote)	Data Entry: Aug/24/2020	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-25-2020 14:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: Aug/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-25-2020 14:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-25-2020 14:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1.a

Date	Location	User	Value	Reason
Aug-25-2020 14:48:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T MIGRAINES erm: Start Date: UNK/UNK/2 003 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:48:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 14:48:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: MIGRAINES	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:48:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/2003	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:48:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.b

Date	Location	User	Value	Reason
Aug-25-2020 14:49:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical History Term: MUSCLE SPASMS (BACK AND SHOULDERS) Start Date: UNK/UNK/2003 Ongoing: YES	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061094**Generated By:** pfe.levisse**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04***I.b Line/MH Number:***

Date	Location	User	Value	Reason
Aug-25-2020 14:49:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 02:47:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Closed	Response satisfies query
Sep-08-2020 15:03:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Related to MedHx Item #1
Sep-04-2020 00:02:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddy51)	Query 1: Opened	ClinQuery: Muscle Spasms: Please can you confirm if a diagnosis is available for this medhx?
Sep-03-2020 18:50:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Candidate	ClinQuery: Muscle Spasms: Please can you confirm if a diagnosis is available for this medhx?
Aug-25-2020 14:49:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe.mgrote)	Data Entry: MUSCLE SPASMS (BACK AN D SHOULDERS)	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:49:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/2003	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

Aug-25-2020 14:49:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry
--	-----------------	---------------------------------	---------------------------	---------------

I.c

Date	Location	User	Value	Reason
Aug-25-2020 14:49:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3 : Medical History T MILD ASTH erm: MA Start Date: UNK/UNK/1 990 Ongoing: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1006
Subject No: 10061094
Generated By: pfe.levisse
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:04

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:49:31 (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-25-2020 14:49:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: MILD ASTHMA	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:49:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/1990	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:49:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-25-2020 14:49:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: SEASONAL ALLERGIES Start Date: UNK/UNK/1988 Ongoing: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:49:54 (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-25-2020 14:49:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: SEASONAL ALLERGIES	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:49:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/1988	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:49:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Aug-25-2020 14:50:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 5 Number: Medical History OPSTURAL ORTHOS TATIC TACHYCHAR Term: DIA SYNDROME Start Dat UNK/UNK/1986 e: Ongoing YES :	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:50:50 (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-25-2020 14:50:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: OPSTURAL ORTHOSTATIC TA CHYCHARDIA SYNDROME	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:50:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/1986	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:50:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Aug-25-2020 14:52:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 6 mber: Medical Hist EHLRS DAULOS ory Term: SYNDROME Start Date: UNK/UNK/1986 Ongoing: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:52:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 14:52:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	<u>Data Entry:</u> EHLRS DAULOS SYNDROME	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:52:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	<u>Data Entry:</u> UNK/UNK/1986	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:52:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	<u>Data Entry:</u> YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Aug-25-2020 14:52:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH N umber: Medical Hi story Term : POST TRAUMATIC STRESS DISORDE R Start Date: UNK/UNK/1980 Ongoing: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:52:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 14:52:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	<u>Data Entry:</u> POST TRAUMATIC STRESS DISORDER	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:52:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	<u>Data Entry:</u> UNK/UNK/1980	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:52:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	<u>Data Entry:</u> YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Sep-01-2020 12:43:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe.mgrote)	<u>Data Entry:</u> Line/MH Number: 8 Medical History Term: DIFFUSE SPASTIC ESOPHAGUS Start Date: UNK/UNK/2015 Ongoing: YES	Changed Information
Aug-25-2020 14:53:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 8	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

			Medical History Term: DIFFUSE SPASTIC ESOPHAGITIS	
			Start Date: UNK/UNK/2015	
			Ongoing: YES	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:53:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-01-2020 15:55:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Sep-01-2020 12:43:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-01-2020 12:43:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: DIFFUSE SPASTIC ESOPHAGUS	Changed Information
Aug-25-2020 22:59:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify DIFFUSE SPASTIC ESOPHAGITIS as follows...Term is unclear. Are you reporting DIFFUSE SPASM ESOPHAGEAL? Or ESOPHAGITIS? Or other? Please update the verbatim term to clarify. Thank you.
Aug-25-2020	ACV0PFEINFP6000	Maddie Grote	Data Entry:	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

14:53:17 (UTC-07:00) Mountain Time (US & Canada)		(pfe mgrote)	DIFFUSE S PASTIC ES OPHAGITIS	
---	--	--------------	-------------------------------------	--

I.h Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:53:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/2015	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:53:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Aug-25-2020 14:54:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: ORAL COLD S ORES Start Date: UNK/UNK/199 5 Ongoing: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:54:02 (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
Oct-29-2020 02:06:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madar)	Query 1: Closed	Response satisfies query
Oct-27-2020 16:09:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	No active cold sores at time of study entry per Physical Exam performed.
Oct-24-2020 22:01:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (pfe.dychts)	Query 1: Opened	GPD Clin: Did the subject have active cold sores when entering the study or are if not present, was it intermittent?
Aug-25-2020 14:54:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe.mgrote)	Data Entry: ORAL COLD SORES	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:54:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe.mgrote)	Data Entry: UNK/UNK/1995	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:54:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe.mgrote)	Data Entry: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.j

Date	Location	User	Value	Reason
Aug-25-2020 14:54:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 10 mber: Medical Hist ATTENTION DEF ory Term: CIT DISORDER Start Date: UNK/UNK/1998 Ongoing: YES	Initial Entry

I.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:54:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 14:54:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: ATTENTION DEFICIT DISORD ER	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:54:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/1998	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:54:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

I.k

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

Aug-25-2020 14:55:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 11 Number: Medical TEMPORPMANDIB History T ULAR JOINT DYSF erm: UNCTION Start Date UNK/UNK/2003 : Ongoing: YES	Initial Entry
--	-----------------	-------------------------	---	---------------

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:55:21 (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
Aug-25-2020 14:55:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: TEMPORPMANDIBULAR JOI NT DYSFUNCTION	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:55:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/2003	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:55:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Aug-25-2020 14:56:05	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

(UTC-07:00) Mountain Time (US & Canada)		(autocalc)	Line/MH Number: 12	
			Medical History Term: NISSEN FUNDIPLICATION	
			Start Date: UNK/UNK/2009	
			Ongoing: YES	

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:56:05 (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
Aug-25-2020 14:56:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: NISSEN FUNDIPLICATION	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:56:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/2009	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:56:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

1.m

Date	Location	User	Value	Reason
Aug-25-2020 14:56:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

			Medical History Term GASTROESOPHAG EAL REFLUX DISE : ASE Start Date: UNK/UNK/1986 Ongoing: YES	
--	--	--	---	--

I.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:56:31 (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
Aug-25-2020 14:56:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: GASTROESOPHAGEAL REFLUX DISEASE	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:56:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/1986	Initial Entry

I.m Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:56:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

I.n

Date	Location	User	Value	Reason
Aug-25-2020 14:57:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 14 Medical History Term: DEVIATED SEPTUM	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

			Start Date: UNK/UNK/1987 Ongoing: NO End Date: UNK/UNK/2004	
--	--	--	--	--

I.n Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:57:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 14:57:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: DEVIATED SEPTUM	Initial Entry

I.n Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:57:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/1987	Initial Entry

I.n Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:57:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: NO End Date: UNK/UNK/2004	Initial Entry

I.o

Date	Location	User	Value	Reason
Aug-25-2020 16:02:41	ACV0PFEINFP6000	Maddie	Data Entry:	Changed

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

(UTC-07:00) Mountain Time (US & Canada)		Grote (pfe.mgrote)	Line/MH Number: 15 Medical History Term: HEART MUR MUR Start Date: UNK/UNK/2019 Ongoing: YES	Information
Aug-25-2020 14:58:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 15 Medical History Term: HEART MUR MUR Start Date: UNK/UNK/2020 Ongoing: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.o Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:58:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 14:58:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe.mgrote)	Data Entry: HEART MURMUR	Initial Entry

I.o Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 16:02:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-25-2020 16:02:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe.mgrote)	Data Entry: UNK/UNK/2019	Changed Information
Aug-25-2020 16:00:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Start Date is after or equal to the first vaccination date 24/Aug/2020. Please review and update as appropriate.
Aug-25-2020 14:58:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe.mgrote)	Data Entry: UNK/UNK/2020	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:58:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe.mgrote)	Data Entry: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.p

Date	Location	User	Value	Reason
Aug-25-2020 14:58:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 16 Medical History Term: DEVIATED SEPTUM REPAIR Start Date: UNK/UNK/2004 Ongoing: NO End Date: UNK/UNK/2004	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.p Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 14:58:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 14:58:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: DEVIATED SEPTUM REPAIR	Initial Entry

I.p Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:58:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/2004	Initial Entry

I.p Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 14:58:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: NO End Date: UNK/UNK/2004	Initial Entry

I.q

Date	Location	User	Value	Reason
Aug-27-2020 09:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 17 : Medical History T ACNE (FACI erm: AL) Start Date: UNK/UNK/1 998 Ongoing: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

1.q Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 09:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 09:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: ACNE (FACIAL)	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 09:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/1998	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

I.q Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 09:45:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

I.r

Date	Location	User	Value	Reason
Aug-27-2020 09:45:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 18 mber: Medical Histo AMOXICILLIN ry Term: ALLERGY Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.r Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 09:45:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 09:45:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: AMOXICILLIN ALLERGY	Initial Entry

I.r Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 09:45:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/1990	Initial Entry

I.r Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 09:45:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

I.s

Date	Location	User	Value	Reason
Aug-27-2020 09:46:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 19 Number: Medical Hi IODINATED CONT story Term RAST MEDIA ALL : ERGY Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.s Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 09:46:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 09:46:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: IODINATED CONTRAST MEDI A ALLERGY	Initial Entry

I.s Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 09:46:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/1990	Initial Entry

I.s Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 09:46:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

I.t

Date	Location	User	Value	Reason
Aug-27-2020 09:46:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 20 ber: Medical Histo PENICILLIN G ry Term: ALLERGY Start Date: UNK/UNK/1990 Ongoing: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.t Line/MH Number:

Date	Location	User	Value	Reason
Aug-27-2020 09:46:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 09:46:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: PENICILLIN G ALLERGY	Initial Entry

I.t Start Date:

Date	Location	User	Value	Reason
Aug-27-2020 09:46:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: UNK/UNK/1990	Initial Entry

I.t Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 09:46:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

I.u

Date	Location	User	Value	Reason
Oct-21-2020 15:24:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 21 ber: Medical Histor RECURRENT SI y Term: NUSITIS Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

I.u Line/MH Number:

Date	Location	User	Value	Reason
Oct-21-2020 15:24:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

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

Date	Location	User	Value	Reason
Oct-21-2020 15:24:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: RECURRENT SINUSITIS	Initial Entry

I.u Start Date:

Date	Location	User	Value	Reason
Oct-21-2020 15:24:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: UNK/UNK/2010	Initial Entry

I.u Ongoing:

Date	Location	User	Value	Reason
Oct-21-2020 15:24:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1006

Subject No: 10061094

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: Aug/24/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: 137.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: 69.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:40 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20.3	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

Time (US & Canada)				
--------------------	--	--	--	--

7.a

Date	Location	User	Value	Reason
Aug-25-2020 14:59:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: Record Identifier: 1 : Temperature: 98.1 Temperature Unit F : Temperature Loca ORAL CAV tion:: ITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: 98.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:47 (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
Aug-25-2020 14:59:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: Aug/24/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-25-2020 14:59:47 (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
Aug-25-2020 14:59:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-25-2020 14:59:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
--	-----------------	-------------------------	--	---------------

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:47 (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-25-2020 14:59:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-25-2020 14:59:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-25-2020 15:59:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: Aug/24/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-25-2020 15:59:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: 61617	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 15:59:38 (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-25-2020 15:59:38 (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-26-2020 08:30:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-25-2020 21:44:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 15:59:38 (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-25-2020 15:59:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe.mgrote)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Aug-26-2020 08:30:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BHV2Y9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:30:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BHV2Y9	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-26-2020 08:30:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BHV2YB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:30:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BHV2YB	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-26-2020 08:30:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BHV2YC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:30:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BHV2YC	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

5.d

Date	Location	User	Value	Reason
Aug-26-2020 08:34:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BJ7LY9	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:34:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BJ7LY9	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-26-2020 08:34:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BJ7LYB	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:34:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BJ7LYB	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 15:59:56 (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-25-2020 15:59:56 (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-26-2020 08:31:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-25-2020 21:43:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 15:59:56 (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-25-2020 15:59:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe.mgrote)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Aug-26-2020 08:31:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BHV2PV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:31:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BHV2PV	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061094

Generated By: pfe.lewissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-25-2020 16:00:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-25-2020 16:00:34 (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-25-2020 16:00:34 (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-25-2020 16:00:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: Aug/24/2020 09:46	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-25-2020 16:00:34 (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
Aug-25-2020 16:00:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote	Data Entry: LEFT	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:04
Site No: 1006
Subject No: 10061094
Generated By: pfe.levissc
Form: VACCINATION - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:04

Time (US & Canada)		(pfe mgrote)	
--------------------	--	--------------	--

7. Route:

Date	Location	User	Value	Reason
Aug-25-2020 16:00:34 (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-25-2020 16:00:34 (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
Aug-25-2020 16:00:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-25-2020 16:00:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Maddie Grote (pfe mgrote)	Data Entry: NO - REACTOGENICITY E-DI ARY NOT COLLECTED FOR T HIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-23-2020 13:12:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 2: Clos ed	Response satisfies query
Oct-23-2020 12:42:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 2: Ans wered	Original value is correct
Oct-22-2020 04:19:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Ope ned	DMW5127505;The Date of Visit at Visit V2_VAX2_L is the same as the other Date of Visit at Visit COVID_A. Please review for duplication and update as appropriate.
Sep-23-2020 01:53:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Pankaj Bhoir (pfe.bhoirp02)	Query 1: Clos ed	Response satisfies query
Sep-22-2020 15:01:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Ans wered	Confirm visit OOV, protocol deviation to be submitted
Sep-21-2020 03:05:52	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Ope	PDQ: DOV at this visit is out of

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

(UTC-07:00) Mountain Time (US & Canada)			ned	window (2 day) from DOV (24/Aug /2020) at V1D1VX1L. Please either update DOV or confirm whether visit is out of window due to temporary delay of vaccination/ else provide details as appropriate.
Sep-18-2020 14:37:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Sep/18/ 2020	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-18-2020 14:37:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Sep/18/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-18-2020 14:37:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Record Identifier: 1 : Temperature: 97.5 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-18-2020 14:37:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-18-2020 14:37:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-18-2020 14:37:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: F	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-18-2020 14:37:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-18-2020 14:37:50 (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-18-2020 14:37:50 (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-18-2020 14:37:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Sep/18/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-18-2020 14:37:50 (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-18-2020 14:37:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-18-2020 14:37:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 113 Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE Not Done::	Initial Entry
--	-----------------	-------------------------	--	---------------

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-18-2020 14:37:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-18-2020 14:37:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-18-2020 14:37:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-18-2020 12:50:56 (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-18-2020 12:50:56 (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
Oct-23-2020 14:22:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Oct-23-2020 14:22:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Oct-23-2020 14:22:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Changed Information
Oct-23-2020 13:40:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Carrie Nedrick (pfe.nedricke)	Query 3: Closed	Response satisfies query

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061094**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

Oct-23-2020 12:43:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 3: Answered	V2 Swab captured on COVID_A Visit
Oct-22-2020 08:57:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Carrie Nedrick (pfe.nedrickc)	Query 3: Opened	DM: 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-21-2020 17:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-21-2020 17:19:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-21-2020 15:44:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 12:51:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-18-2020 12:50:56 (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-18-2020 12:50:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES Date of Collection: Sep/18/2020	Initial Entry

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-23-2020 14:22:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: SAMPLE CAPTURED IN COVID ILLNESS VISIT A	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 17:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BH2422	Swab barcode captured in Potential COVID-19 Illness A (DELETED)
Oct-21-2020 17:19:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BH2422	Initial Entry
Oct-21-2020 15:44:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID:	Swab barcode captured on Potential COVID-19 Illness A.
Sep-18-2020 12:51:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BH2422	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-25-2020 01:54:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vijay Venugopal (pfe.venugv04)	Query 1: Closed	Response satisfies query
Oct-23-2020 12:51:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	BARCODE DELETED FROM V2

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-21-2020 20:46:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Ope ned	DMW5127319;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-21-2020 17:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data E ntry: BH242 2	Swab barcode captured in Potential COVID-19 Illness A (DELETED)
Oct-21-2020 17:19:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data E ntry: BH242 2	Initial Entry
Oct-21-2020 15:44:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data E ntry:	Swab barcode captured on Potential COVID-19 Illness A.
Sep-18-2020 12:51:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data E ntry: BH242 2	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-18-2020 14:38:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-18-2020 14:38:40 (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-18-2020 14:38:40 (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-18-2020 14:38:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Sep/18/2020 13:29	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-18-2020 14:38:40 (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
Sep-18-2020 14:38:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: LEFT	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

Time (US & Canada)				
--------------------	--	--	--	--

7. Route:

Date	Location	User	Value	Reason
Sep-18-2020 14:38:40 (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-18-2020 14:38:40 (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-18-2020 14:38:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-16-2020 14:54:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ashley Bragg (pfe.abragg)	Data Entry: Oct/16/2020	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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-16-2020 14:55:01 (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-16-2020 14:55:01 (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-16-2020 18:22:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-16-2020 14:55:01 (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-16-2020 14:55:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ashley Bragg (pfe.abragg)	Data Entry: YES Date of Collection: Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 18:22:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Sample ID: BCT8DR	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 18:22:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: BCT8DR	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-16-2020 18:22:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Sample ID: BJ7M85	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 18:22:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: BJ7M85	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-16-2020 18:22:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Sample ID: BJ7MF6	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 18:22:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: BJ7MF6	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 11:07:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Mar/12/2021	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-12-2021 11:08:03 (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-12-2021 11:08:03 (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-12-2021 11:09:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-12-2021 11:08:03 (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-12-2021 11:08:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES Date of Collection: Mar/12/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-12-2021 11:09:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Sample ID: BRBMGO	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 11:09:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: BRBMG0	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-12-2021 11:09:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Sample ID: BS8WM8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 11:09:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: BS8WM8	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-12-2021 11:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Sample ID: BS8WPN	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 11:10:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: BS8WPN	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Sep/18/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-23-2020 13:14:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Pamela Benne prod (pfe.bennep07)	Query 3: Clos ed	Response satisfies query
Oct-23-2020 12:44:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 3: Ans wered	Original value is correct
Oct-22-2020 04:19:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 3: Ope ned	DMW5127504;The Date of Visit at Visit COVID_A is the same as the other Date of Visit at Visit V2_VAX2_L. Please review for duplication and update as appropriate.
Oct-21-2020 15:34:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Dele ted	Close Auto Query
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Dele ted	Close Auto Query

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Sep/18/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061094**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

Oct-21-2020 15:31:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Cand idate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-21-2020 15:31:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Cand idate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-21-2020 15:31:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data E ntry: Sep/18/ 2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-21-2020 15:31:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020**Form Version:** 10-Oct-2020 16:02**Site No:** 1006**Subject No:** 10061094**Generated By:** pfe.levissc**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Oct-21-2020 15:32:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate.
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sep/18/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sep/10/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO Date of Last Symptom Resolved : Sep/15/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan	Data Entry:	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lévissc

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

Time (US & Canada)		(pfe.lbevan)	Symptoms: FEVER Symptom Present: NO	
--------------------	--	--------------	--	--

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.c

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom NO Present:	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms NEW LOSS OF TA : STE OR SMELL Symptom NO Present:	Initial Entry
--	-----------------	----------------------------------	---	---------------

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NEW LOSS OF TASTE OR SME LL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptom NEW OR INCREAS s: ED SORE THROAT Symptom NO Present:	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

4.g Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NEW OR INCREASED SORE T HROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: VOMITING	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

			Symptom Present: NO	
--	--	--	---------------------	--

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-21-2020 15:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 15:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms - Other: NASAL CONGESTION	Transcription Error
Oct-21-2020 15:32:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms - Other: NASAL DISCHARGE	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-21-2020 15:32:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NASAL CONGESTION	Transcription Error
Oct-21-2020 15:32:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NASAL DISCHARGE	Initial Entry

5.b

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-23-2020 12:45:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptom NASAL DISCHARG s - Other: E DISCOLORATIO N	Changed Information
Oct-21-2020 15:32:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms - DISCOLORED Other: MUCUS	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-23-2020 21:42:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Oct-23-2020 12:45:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-23-2020 12:45:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NASAL DISCHARGE DISCOLORATION	Changed Information
Oct-22-2020 02:07:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify DISCOLORED MUCUS as follows...The term is ambiguous. Are you reporting NASAL DISCHARGE DISCOLORATION? SPUTUM DISCOLORED? If so, update the verbatim term as such. Otherwise clarify and edit the term. Thank you.
Oct-21-2020 15:32:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: DISCOLORED MUCUS	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/18/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry
--	-----------------	----------------------------------	--------------------------------	---------------

7. Test Result:

Date	Location	User	Value	Reason
Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Oct-21-2020 15:33:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-21-2020 15:33:31 (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-21-2020 15:33:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-21-2020 15:33:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-21-2020 15:33:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: SWAB PFE COLLECTED AT VI SIT 2	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061094**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-21-2020 15:34:11 (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-21-2020 15:34:11 (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
Oct-21-2020 15:34:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-21-2020 15:34:11 (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-21-2020 15:34:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES Date of Collection: Sep/18/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 15:34:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BH2422	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-23-2020 13:41:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Carrie Nedrick (pfe.nedrickc)	Query 2: Clo sed	Response satisfies query
Oct-23-2020 12:45:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 2: An swere d	BARCODE DELETED FOR V2
Oct-22-2020 23:41:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (pfe.dubeys27)	Query 2: Op ened	HOLDS query: As per LAB, NASAL SWAB sample with barcode BH2422 is received for visit V2_VAX2_L. If InForm data is correct kindly submit SCF to update the visit in Lab. Else clarify.
Oct-22-2020 01:44:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-21-2020 20:46:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW5127318;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-21-2020 15:34:17	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Sep/18/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

(UTC-07:00)
Mountain
Time (US &
Canada)

⋮
BH24
22

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/18/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/18/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.lévissc

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

I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/18/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

I.d

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Type of Practitioner : URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/18/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or Contacts: NO	Initial Entry

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/18/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-21-2020 15:34:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry
--	-----------------	----------------------------------	--------------------------	---------------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Sep/18/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-21-2020 15:35:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNES S	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Oct-24-2020 07:55:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Closed	Thank you.
Oct-23-2020 13:04:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-23-2020 13:04:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> UPPER RESPIRATORY TR ACT INFECTION Date of Diagnosis: Sep/18/2020	Transcription Error
Oct-23-2020 12:52:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Reissued:Opened	CLINQUERY: Thank you. UPPER RESPIRATORY TRACT INFECTION is now documented under this COVID Illness POT ILL CRF. PP Section 8.37, events consistent with the clinical endpoint definition are not to then also be

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Sep/18/2020**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061094**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

				recorded as AEs. Update AE CRF as appropriate.
Oct-23-2020 12:47:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-23-2020 12:47:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> UPPER RESPIRATORY TR ACT INFECTION Date of Diagnosis: Sep/10/2020	Changed Information
Oct-22-2020 09:41:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Opened	CLINQUERY: UPPER RESPIRATORY TRACT INFECTION is reported on AE CRF which overlaps with COVID ILL visit symptom dates. Was diagnosis made? Enter diagnosis of event if available even if diagnosis is not COVID- 19/respiratory related. Update if appropriate
Oct-21-2020 15:35:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-21-2020 15:35:10 (UTC-07:00) Mountain	ACV0PFEINFP6000	Lindsey Bevan	Data Entry: 2	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Sep/18/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)

(pfe.lbevan)

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Oct/22/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Oct-22-2020 18:11:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe.mgrimmatt)	Data Entry: Oct/22/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-22-2020 18:11:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe.mgrimmatt)	Data Entry: COVID_A1	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Oct/22/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061094**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-22-2020 18:12:07 (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-22-2020 18:12:07 (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-22-2020 18:15:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 18:12:07 (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-22-2020 18:12:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe.mgrimmnett)	Data Entry: YES Date of Collection: Oct/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 18:15:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe.mgrimmnett)	Data Entry: Sample ID: BH2442	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Oct/22/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 18:15:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe.mgrimmatt)	Data Entry: BH2442	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-22-2020 18:15:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe.mgrimmatt)	Data Entry: Sample ID: BSJPKD	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 18:15:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe.mgrimmatt)	Data Entry: BSJPKD	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-22-2020 18:15:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe.mgrimmatt)	Data Entry: Sample ID: BJ7MG7	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 18:15:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe.mgrimmatt)	Data Entry: BJ7MG7	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-16-2020 15:18:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Oct/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-16-2020 15:18:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-16-2020 15:18:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-23-2020 13:05:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Deleted	CAPTURED AS COVID_A
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Form Created	

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Form Created	

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-25-2020 14:23:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 2: Closed	Response satisfies query
Oct-19-2020 17:11:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Query 2: Answered	awaiting information from subject and then will update
Oct-15-2020 20:32:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 2: Reissued:Opened	Clin: Please complete the COVID Illness CRF forms.
Oct-15-2020 12:55:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Query 2: Answered	AE occurred prior to protocol amendment 6 approval and irrespective of perceived etiology, was not included in protocol amendment 5. Investigator

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

				deemed AE not a COVID-like illness.
Oct-14-2020 22:30:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 2: Opened	Clin: Per protocol section 8.1., potential COVID-19 related URI (fever, cough, sore throat?), should have please triggered a COVID Illness Visit irrespective of perceived etiology or clinical significance. Please complete the COVID Illness CRF forms
Oct-14-2020 12:45:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 2: Candidate	Clin: Per protocol section 8.1., potential COVID-19 related URI (fever, cough, sore throat?), should have please triggered a COVID Illness Visit irrespective of perceived etiology or clinical significance. Please complete the COVID Illness CRF forms
Sep-23-2020 19:35:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 1: Closed	Response satisfies query
Sep-22-2020 15:08:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Upper Respiratory Tract Infection	Changed Information

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

Sep-22-2020 15:00:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Not considered a potential COVID-19 illness
Sep-21-2020 19:56:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe huh17)	Query 1: Opened	ClinQuery: Per protocol section 8.1, please consider whether this symptom could have been due to COVID-19 and should have triggered a potential illness visit?
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Sinus Infection	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Sep/10/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NO End Date Time: Sep/15/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: 2	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

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
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NO	Initial Entry

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
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-25-2020 02:56:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sakshi Sarmalkar LDM (pfe.sarmas06_ldm)	Query 1: Closed	Response satisfies query
Sep-24-2020 09:48:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	No other symptoms to report
Sep-23-2020 23:55:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1: Reissued: Opened	DM: Thank you for response. However please review in the comment field

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

Canada)				URI-viral is entered, kindly confirm if any other symptoms, AEs or other data should be collected. If yes, please update the CRF as required. Else confirm in query response.
Sep-23-2020 10:55:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-23-2020 10:55:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> URI-VIRAL	Transcription Error

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

Sep-22-2020 06:07:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Reissued: Opened	DM: Per CRF, 'If not related to study treatment other' field, in the comment field 'UPPER RESPIRATORY TRACT INFECTION' is entered. Please confirm any symptoms, AEs or other key data should be collected. If yes then update CRF as needed. Else clarify.
Sep-21-2020 14:37:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-21-2020 14:37:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NOT RELATED If Not Related to study treatment(s), th is event is due to: OTHER <i>If Other, specify</i>	Transcription Error

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1006
Subject No: 10061094
Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Status: Data Complete, Deleted
Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:04

*** THIS REPEATING FORM HAS BEEN DELETED ***

			fy: UP PE R RE SP IR AT OR Y TR AC TI NF EC TI O N	
Sep-20-2020 23:57:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [uri]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[birads02 SDQ=9145]"
Sep-18-2020 14:41:00 (UTC-07:00) Mountain Time (US &	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Ent ry: NOT RE LATED If Not	Transcription Error

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

Canada)			Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> URI	
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Deleted

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

*** THIS REPEATING FORM HAS BEEN DELETED ***

Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry
--	-----------------	--------------------------	---------------------------	---------------

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

Date	Location	User	Value	Reason
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	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
Sep-18-2020 14:40:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NO	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-21-2020 14:37:57 (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
Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: INJECTION SITE PAIN	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sep/19/2020 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO End Date Time: Sep/20/2020 18:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: 1	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
Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

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
Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry
--	-----------------	----------------------------------	--------------------------	---------------

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	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
Sep-21-2020 14:37:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-21-2020 14:38:31 (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
Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: FEVER	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sep/19/2020 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO End Date Time: Sep/20/2020 18:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	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
Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

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
Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES	Initial Entry
--	-----------------	----------------------------------	---------------------------	---------------

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	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
Sep-21-2020 14:38:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Sep-21-2020 14:39:12 (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
Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: GENERALIZED ACHES	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sep/19/2020 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO End Date Time: Sep/20/2020 18:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: 1	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
Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

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
Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry
--	-----------------	----------------------------------	--------------------------	---------------

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	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
Sep-21-2020 14:39:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-07-2021 17:51:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	Response satisfies query
Jan-05-2021 16:51:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 3: Answered	Safety updated
Jan-05-2021 06:33:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Closed	acceptable discrepancy
Dec-31-2020 00:15:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Reissued:Candid ate	PSSR Review
Dec-30-2020 10:30:25 (UTC-07:00) Mountain Time (US	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 4: Answered	Update sent on 17DEC2020 at 17:04

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

& Canada)				
Dec-22-2020 06:19:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Reissued:Open ed	SAE RECON: Term in SDB still recorded as pregnancy. please confirm if follow up AEM form was sent
Dec-18-2020 09:54:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Open ed	CLINICAL please FAX an updated Pregnancy report with the updated event term (Exposure during Pregnancy), this prior pregnancy Hx, the contraceptive method (condom) and any other event updates.
Dec-18-2020 05:29:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Reissued:Candid ate	pending SDB update
Dec-17-2020 16:52:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 4: Answered	Update to be sent today
Dec-17-2020 16:45:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 3: Answered	2019 full term pregnancy and delivery
Dec-17-2020 05:50:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 4: Opened	SAE RECON:AER#2020475689, term in Safety database was recorded as pregnancy. Please confirm if a follow up AEM form was sent to Pfizer safety to update term to Exposure during Pregnancy.
Dec-10-2020 09:08:05	ACV0PFEINFP6000	Kathryn Sewell	Query 3: Opened	Clinical Please submit a PG report safety followup with

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061094**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-07:00) Mountain Time (US & Canada)		(pfe.sewelk02)		the updated event term, condom failure information, and YEAR / OUTCOME for previous pregnancy
Dec-10-2020 09:03:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Dec-10-2020 09:02:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Dec-07-2020 12:24:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Dec-07-2020 12:24:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-07-2020 12:24:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Exposure During Pregnan cy	Changed Information
Dec-03-2020 08:25:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL On SAE med history, please enter the missing year for "1 previous pregnancy, with 1 other children", as part of the relevant obstetric history; also in narrative report the contraceptive [CONDOM]
Dec-03-2020 08:14:39 (UTC-07:00) Mountain Time (US	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL As per CRF CG 8.50.2.5, a healthy pregnancy is not an AE term; instead "Exposure

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

& Canada)				During Pregnancy” will be recorded as an AE
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Pregnancy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Nov/15/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-06-2020 07:56:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Dec-03-2020 13:42:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Dec-03-2020 13:42:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Dec-03-2020 13:42:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry:	Changed Information
Dec-03-2020 08:20:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL QUERY As per CRF CG 8.50.2.5, the toxicity grade

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Verified

Site No: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levisse

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

				for "Exposure During Pregnancy" is reported as Not Applicable
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	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
Dec-06-2020 07:57:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Dec-03-2020 13:41:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Dec-03-2020 13:41:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-03-2020 13:41:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Changed Information
Dec-03-2020 08:18:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL As per CRF CG 8.50.2.5, an "Exposure During Pregnancy" is not an SAE [despite using similar forms to report pregnancy]; only abnormal outcomes of pregnancy are evaluated for serious criteria

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Pregnancy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	<p>Data Entry: YES</p> <p>Is this serious event associated with congenital anomaly or bir th defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>NO</p> <p>Did this serious event result in persistent or significant disabil ity/incapacity?</p> <p>NO</p> <p>Is this serious event life threat ening?</p> <p>NO</p> <p>Other medically important seri ous event</p> <p>YES</p>	Initial Entry

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
------	----------	------	-------	--------

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry
--	-----------------	----------------------------------	--------------------------	---------------

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: condom failure	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Dec-09-2020 03:24:01	ACV0PFEINFP6000	Ricell Ann	Query 1: Closed	Response satisfies

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061094**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

(UTC-07:00) Mountain Time (US & Canada)		Piojo (pfe.quitor)		query
Dec-07-2020 22:44:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 3: Closed	Closed as per site response.
Dec-07-2020 22:25:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bhumika Prabhu (pfe.prabhb)	Query 2: Closed	Response satisfies query
Dec-07-2020 12:25:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 3: Answered	AE ongoing
Dec-07-2020 12:24:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Exposure During Pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Dec-07-2020 12:24:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 2: Answered	AE ongoing
Dec-07-2020 12:23:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Dec-07-2020 12:23:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Dec-07-2020 12:23:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: UNKNOWN	Changed Information
Dec-07-2020 05:48:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotor)	Query 1: Opened	SAE RECON: AER#2020475689, the outcome in AE CRF was reported as NOT RECOVERED/NOT RESOLVED. Per 3 Nov EDP guidance (study communication), outcome should be recorded as UNKNOWN. Please confirm and update accordingly.
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NOT RECOVERED/NOT RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Dec-01-2020 17:39:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Feb-26-2021 08:17:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Feb/2/2021	Transcription Error
Feb-05-2021 14:02:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Feb/5/2021	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Status: Data Complete, Frozen

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-05-2021 14:02:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-05-2021 14:01:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Feb/5/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-05-2021 14:01:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061094

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject Initials: ---

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-16-2020 15:18:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-25-2020 15:59:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Aug-25-2020 14:48:01 (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-16-2020 15:18:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/16/2020	Initial Entry
Aug-25-2020 15:59:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/24/2020	Initial Entry
Aug-25-2020 14:48:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/24/2020	Initial Entry

090177e196ae3d40\Final\Final On: 01-Apr-2021 04:28 (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: 1006

Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic

Subject No: 10061094

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Oct-29-2020 14:11:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	James Peterson (pfe.jpeteron)	Data Entry: Click Here to Enable	Initial Entry