

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: COHORT_SELECTION

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](#)

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	06 OCT 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: 10061176

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT

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](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Oct/13/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10061176]
2.	Birth Date:	(b) (6)/2004
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

Generated By: pfe.lewissc

Form: DATE OF VISIT

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](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

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](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Oct/13/2020
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: 10061176

Generated By: pfe.levisse

Form: GENERAL MEDICAL 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

[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/2017
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Depression]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal Allergies]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001	Form: HIV STATUS
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Frozen, Verified
Form Version: 15-Sep-2020 21:57	Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic
Site No: 1006	Subject Initials: ---
Subject No: 10061176	Generated Time (GMT): 29-Mar-2021 04:04
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

HIV Status		
1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

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

Vital Signs

1.	Date:	Oct/27/2020
2.	Weight:	[140.3]
3.	Unit:	LB
4.	Height:	[63.0]
5.	Unit:	in
6.	Body Mass Index:	[24.9]

Vital Signs Details

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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](#)

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/27/2020
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:	

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001	Form: RANDOMIZATION
Visit: V1_DAY1_VAX1_L	Form Status: Data Complete, Frozen, Verified
Form Version: 22-Apr-2020 21:03	Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic
Site No: 1006	Subject Initials: ---
Subject No: 10061176	Generated Time (GMT): 29-Mar-2021 04:04
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

Disposition		
1.	Randomization Date :	Oct/27/2020
2.	Randomization Number:	[105602]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BH244F]
5.b	Sample ID	[BSJPKS]
5.c	Sample ID	[BJ7MGL]

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BH249Z]
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090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: VACCINATION

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

Vaccination

1.	Was there a temporary delay of vaccination?	YES Date of First Delay: Oct/13/2020 Reason(s) for Temporary Delay of Vaccination RECENT NON-STUDY VACCINATION
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/27/2020 17:59
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

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

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](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

Generated By: pfe.lewissc

Form: DATE OF VISIT

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/19/2020
2.	Erroneous Visit	

Header Text: c4591001
Visit: V2_VAX2_L **Form:** VITAL SIGNS - TEMP
Form Version: 10-Oct-2020 16:01 **Form Status:** Data Complete, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061176 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

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

Vital Signs

1.	Date:	Nov/19/2020	Comments
----	-------	-------------	--------------------------

Vital Signs Details

2.a	Record Identifier:	1	
	Temperature:	[97.7]	Comments
	Unit:	F	Comments
	Temperature Location:	ORAL CAVITY	Comments

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 15:58

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

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

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

Lab Urinalysis

1.	Lab Panel:	URINALYSIS	Comments
2.	Lab Sub-Panel:	PREGNANCY	Comments
3.	Collection Date:	Nov/19/2020	Comments
4.	Laboratory Name and Address (Derived)	[STUDY SITE]	Comments
5.	Specimen Type:	URINE	Comments

Lab Result

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

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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

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

Electronic Sample Tracking

1.	Data Origin	SITE	Comments
2.	Sample Type	NASAL_SWAB	Comments
3.	Sample Collected?	YES Date of Collection: Nov/19/2020	Comments
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]	Comments

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BH24BB]
5.b	Sample ID	[]

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001
Visit: V2_VAX2_L **Form:** VACCINATION
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: 10061176 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

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

Vaccination			
1.	Was there a temporary delay of vaccination?	NO	Comments
2.	Treatment Name	[BLINDED THERAPY]	Comments
3.	Formulation:	INJECTION	Comments
4.	Dose Date Time:	Nov/19/2020 17:41	Comments
5.	Anatomical Location:	DELTOID MUSCLE	Comments
6.	Body Side:	LEFT	Comments
7.	Route:	INTRAMUSCULAR	Comments
8.	Actual Dose:	[]	Comments
9.	Unit:		Comments
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Comments
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES	Comments

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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: 10061176

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	Dec/29/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/29/2020
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	[BRL0TR]
5.b	Sample ID	[BJ7MP8]
5.c	Sample ID	[BJ7ML8]

090177e196ae3d3f\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: 10061176

Generated By: pfe.lewissc

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: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

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	[]
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Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

Generated By: pfe.lewissc

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: 10061176

Generated By: pfe.levisse

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	[]
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Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

Generated By: pfe.lewissc

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	

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

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	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** DATE OF VISIT - ILLNESS ONSET

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/11/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

eCRF Audit Trail History

Signs and Symptoms

1.	Date of Assessment:	Nov/11/2020
2.	Date of First Symptom Started:	Nov/10/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/20/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	YES
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?	YES
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.	Symptoms - Other Text:	[]
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090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3d3fFinal\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Nov/11/2020

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: 10061176

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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?	YES Date of Collection: Nov/11/2020
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	[CV49749]
-----	-----------	-----------

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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:	[Telehealth visit]

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Not Complete

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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:	NO
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
----	--	----

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1. DELETED	HOSPITALIZATION STATUS	HOSPITAL	Feb/8/2021	NO Discharge Date: Feb/10/2021	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS
Nov/11/2020

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

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

Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Feb/8/2021
4.	Ongoing?	NO Discharge Date: Feb/10/2021

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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 on **Form:** RESPIRATORY TREATMENT
Nov/11/2020

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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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 on Nov/11/2020 **Form:** ILLNESS DETAILS

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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?	NO
3.	Toxicity Grade:	1

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** ILLNESS DETAILS - SEVERE

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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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: 10-Oct-2020 15:58

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Not Started

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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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

090177e196ae3d3f\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: 10-Oct-2020 16:02

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Not Started

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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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

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

#	Date:	Vital Signs Details			Form Instance
1.	Feb/8/2021	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	105	67	

090177e196ae3d3fFinalFinal On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Nov/11/2020

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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Vital Signs

1.	Date:	Feb/8/2021
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	Systolic:	[105]
	Diastolic:	[67]
	Respiratory Rate in respirations/minute:	[22]
	Heart Rate in beats/minute:	[133]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

#	Date:	Vital Signs Details		Form Instance
1.	Feb/8/2021	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	91.0	

090177e196ae3d3fFinal\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on
Nov/11/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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Vital Signs

1.	Date:	Feb/8/2021
----	-------	------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[91.0]

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3d3fFinal\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** OXYGENATION PARAMETERS

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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Concomitant Medications

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

090177e196ae3d3f\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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Nov/11/2020

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** DATE OF VISIT - ILLNESS ONSET

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/10/2021
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_B
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Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**eCRF Audit Trail History****Signs and Symptoms**

1.	Date of Assessment:	Feb/10/2021
2.	Date of First Symptom Started:	Feb/3/2021
3.	Symptoms Ongoing?	YES

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?	YES
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?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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.	Feb/8/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	Repeating Pages

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** MICROBIOLOGY SPECIMEN

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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Microbiology Specimen

1.	Actual Date of Collection:	Feb/8/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings/Details:	[]
9.	Trade Name Other, Specify:	[clia certified]

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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?	YES Date of Collection: Feb/10/2021
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	[CV46529]
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090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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:	[self swab]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** HEALTH CARE UTILIZATION

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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:	YES Number of Visits or Contacts: [1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
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?	YES Has the subject been in intensive care due to potential COVID-19 illness? NO
----	--	--

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Feb/8/2021	NO Discharge Date: Feb/10/2021	Repeating Pages

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** HOSPITALIZATION DETAILS

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Feb/8/2021
4.	Ongoing?	NO Discharge Date: Feb/10/2021

Header Text: c4591001

Visit: POT_COVID_ILL 2

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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 2 - Unscheduled Visit on Feb/10/2021 **Form:** RESPIRATORY TREATMENT

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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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 2 - Unscheduled Visit on Feb/10/2021 **Form:** ILLNESS DETAILS

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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: [strep throat] Date of Diagnosis: Feb/8/2021
3.	Toxicity Grade:	3

Header Text: c4591001

Visit: POT_COVID_ILL 2

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** ILLNESS DETAILS - SEVERE

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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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 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Form Status: Not Started

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 10-Oct-2020 16:02

Form Status: Not Started

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 10-Oct-2020 15:59

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Feb/10/2021

Form Version: 10-Oct-2020 15:59

Form Status: Not Started

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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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 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d3fFinal\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Form Status: Not Started

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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Vital Signs

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

Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 2

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** OXYGENATION PARAMETERS

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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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 2

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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 2 - Unscheduled Visit on Feb/10/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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Concomitant Medications

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on **Form:** IMAGING
Feb/10/2021

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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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 Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Dec/11/2020

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/11/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY on Dec/11/2020

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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: Dec/11/2020
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	[BCSY13]
5.b	Sample ID	[BS8WJ3]
5.c	Sample ID	[BS8WJY]

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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:	
----	-----------------------	--

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still On going	Form Instance
1.	ADVERSE EVENT	1	Acute Asthma Exacerbation	Feb/3/2021 UNK:UNK	NO End Date Time: Feb/10/2021 UNK:UNK	Repeating Pages

090177e196ae3d3f\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: 10061176

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Acute Asthma Exacerbation]
4.	Start Date Time:	Feb/3/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/10/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
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: [strep pharyngitis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae3d3f\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: 10061176

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

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

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	[2021148838]

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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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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: 10061176

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

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Medication Error

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

090177e196ae3d3f\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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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.	1	VACCINATIONS	NO	Influenza Vaccine	Oct/10/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

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

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[Form Audit Trail](#)

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza Vaccine]
5.	Date:	Oct/10/2020

090177e196ae3d3f\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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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. DELETED	1	CORTICOSTEROIDS	NO	Prednisone	30	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Data Complete, Deleted, Frozen, Verified

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 ***

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Concomitant Medications

1.	What is the medication identifier?	[4]
2.	Category:	CORTICOSTEROIDS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Prednisone]
5.	Dose:	[30]
6.	Dose Unit:	mg
7.	Dose Frequency:	BID
8.	Route:	ORAL
9.	Start Date:	Feb/6/2021
10.	Ongoing?	NO End Date: Feb/14/2021

090177e196ae3d3f\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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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: 10061176

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061176

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 - 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: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Unplanned Assessments

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 10061176

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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:	

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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?	

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001	Form: CONTACT OUTCOME - MONTH 1
Visit: Unplanned Vaccination - Unscheduled	Form Status: Not Started
Form Version: 10-Oct-2020 15:57	Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic
Site No: 1006	Subject Initials: ---
Subject No: 10061176	Generated Time (GMT): 29-Mar-2021 04:04
Generated By: pfe.levisse	

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Informed Consent - Asymptomatic Surveillance

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

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

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 :	Dec/29/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

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: 10061176

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	Jan/28/2021
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, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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 per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1006

Subject No: 10061176

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:	[]

090177e196ae3d3f\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: 10061176

Generated By: pfe.lewissc

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/3/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: WITHDRAWAL OF CONSENT

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

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: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Not Started

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

Subject Initials: ---

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

Informed Consent - Further Vaccination

1.	Consent Was:	
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090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Not Started

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

Subject Initials: ---

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

Inclusion Criteria Not Met

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

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	
----	---	--

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

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 - Screening for Further Vaccination

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisc

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	Dec/29/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

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: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

Casebook Signature Form

1.	Casebook Signature	
----	--------------------	--

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

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: 10061176

Subject Initials: ---

Generated By: pfe.levissc

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
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:00

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - Comments

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

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Item	Date	User	Comment
Form	Oct-13-2020 18:01:50 (UTC-07:00) Mountain Time (US & Canada)	Emily Wilcox (pfe.ewilcox)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: DATE OF VISIT - Comments

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](#)

Item	Date	User	Comment
Form	Oct-28-2020 16:29:45 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

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](#)

Item	Date	User	Comment
Form	Nov-23-2020 15:06:23 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
Form	Nov-06-2020 12:27:59 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
Form	Nov-04-2020 09:03:25 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

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](#)

Item	Date	User	Comment
1	Nov-23-2020 15:06:23 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
1	Nov-06-2020 12:27:59 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
1	Nov-04-2020 09:03:25 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

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

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Item	Date	User	Comment
2.a	Nov-23-2020 15:06:23 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
2.a	Nov-06-2020 12:27:59 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
2.a	Nov-04-2020 09:03:25 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

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](#)

Item	Date	User	Comment
2.a	Nov-23-2020 15:06:23 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
2.a	Nov-06-2020 12:27:59 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
2.a	Nov-04-2020 09:03:25 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - Comments

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](#)

Item	Date	User	Comment
2.a	Nov-23-2020 15:06:23 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
2.a	Nov-06-2020 12:27:59 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
2.a	Nov-04-2020 09:03:25 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 15:58

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
Form	Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
Form	Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
Form	Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 15:58

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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

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Item	Date	User	Comment
1	Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
1	Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
1	Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 15:58

Site No: 1006

Subject No: 10061176

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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

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Item	Date	User	Comment
2	Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
2	Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
2	Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 15:58

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

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](#)

Item	Date	User	Comment
3	Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
3	Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
3	Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

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Subject Initials: ---

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Item	Date	User	Comment
4	Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
4	Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
4	Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

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Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

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Item	Date	User	Comment
5	Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
5	Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
5	Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

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Item	Date	User	Comment
6.a	Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
6.a	Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
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Item	Date	User	Comment
Form	Nov-23-2020 15:13:49 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
Form	Nov-03-2020 11:50:35 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable

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Item	Date	User	Comment
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1	Nov-03-2020 11:50:35 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable

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Item	Date	User	Comment
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Item	Date	User	Comment
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Item	Date	User	Comment
6	Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
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6	Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

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Item	Date	User	Comment
7	Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
7	Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
7	Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

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Item	Date	User	Comment
8	Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
8	Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
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Item	Date	User	Comment
9	Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
9	Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
9	Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

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Item	Date	User	Comment
10	Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
10	Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
10	Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

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Item	Date	User	Comment
11	Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	Bradley Young (pfe.byoung)	
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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

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Item	Date	User	Comment
Form	Nov-11-2020 16:10:49 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

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Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
8	Nov-11-2020 16:10:49 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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Item	Date	User	Comment
9	Nov-11-2020 16:10:49 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

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: 10061176

Subject Initials: ---

Generated By: pfe.levissc

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

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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
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Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 10-Oct-2020 16:01

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: COHORT_SELECTION - 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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Oct-13-2020 18:01:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: 06 OCT 2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 18:01:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT - 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

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I. Consent Was:

Date	Location	User	Value	Reason
Oct-29-2020 05:28:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Closed	Response satisfies query
Oct-28-2020 16:33:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Subject met delay criteria
Oct-28-2020 16:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary.
Oct-13-2020 18:01:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: OBTAINED Date Written Consent Obtained Oct/13/2020	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Subject ID

Date	Location	User	Value	Reason
Oct-13-2020 18:00:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 10061176	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Oct-13-2020 18:00:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> (b) (6) /2004	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Oct-13-2020 18:01:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<u>Data Entry:</u> FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Oct-13-2020 18:01:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<u>Data Entry:</u> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Oct-13-2020 18:01:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<u>Data Entry:</u> WHITE	Initial Entry

090177e196ae3d3f\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: 10061176

Generated By: pfe.lewissc

Form: DATE OF VISIT - 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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-29-2020 19:46:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Closed	Auto closed by Validation Check: VC_SV001_02
Oct-29-2020 12:42:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 2: Answered	Date for V2 entered in error
Oct-28-2020 23:31:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Opened	DMW5210935;The Date of Visit at Visit V1_DAY1_VAX1_L is the same as the other Date of Visit at Visit V2_VAX2_L. Please review for duplication and update as appropriate.
Oct-28-2020 16:59:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Christopher Lewis (pfe.lewisc45)	Query 1: Closed	Response satisfies query
Oct-28-2020 16:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-28-2020 16:27:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Oct/27/2020	Changed Information
Oct-28-2020 15:17:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Christopher Lewis (pfe.lewisc45)	Query 1: Opened	Per CRF guidelines if temporary delay occurs DOV should be updated to reflect the date of

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: DATE OF VISIT - 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

				vaccination. This will cure all queries on these pages.
Oct-13-2020 18:01:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Oct/13/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - 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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Oct-13-2020 18:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Oct/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-13-2020 18:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-13-2020 18:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

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I.a

Date	Location	User	Value	Reason
Oct-27-2020 18:13:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Migraines Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Oct-27-2020 18:13:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Oct-27-2020 18:13:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: Migraines	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Oct-27-2020 18:13:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: UNK/UNK/2017	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Oct-27-2020 18:13:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
Oct-27-2020 18:13:31	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

090177e196ae3d3f\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: 10061176

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - 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

(UTC-07:00) Mountain Time (US & Canada)		(autocalc)	Line/MH Number: 2 Medical History Term: Depression Start Date: UNK/UNK/2018 Ongoing: YES	
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I.b Line/MH Number:

Date	Location	User	Value	Reason
Oct-27-2020 18:13:31 (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
Oct-27-2020 18:13:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: Depression	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Oct-27-2020 18:13:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: UNK/UNK/2018	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Oct-27-2020 18:13:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Oct-27-2020 18:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: Anxiety Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Oct-27-2020 18:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Oct-27-2020 18:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: Anxiety	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Oct-27-2020 18:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: UNK/UNK/2018	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Oct-27-2020 18:13:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-27-2020 18:14:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Asthma Start Date: UNK/UNK/2011 Ongoing: YES	Initial Entry

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - 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

I.d Line/MH Number:

Date	Location	User	Value	Reason
Oct-27-2020 18:14:37 (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
Oct-27-2020 18:14:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: Asthma	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Oct-27-2020 18:14:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: UNK/UNK/2011	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Oct-27-2020 18:14:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Oct-27-2020 18:15:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Seasonal Allergies Start Date: UNK/UNK/2011 Ongoing: YES	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - 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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

I.e Line/MH Number:

Date	Location	User	Value	Reason
Oct-27-2020 18:15:03 (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
Oct-27-2020 18:15:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: Seasonal Allergies	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Oct-27-2020 18:15:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: UNK/UNK/2011	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Oct-27-2020 18:15:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: YES	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: HIV STATUS - 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

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1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Oct-27-2020 18:11:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: The subject is NOT known to be HI V POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - 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

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1. Date:

Date	Location	User	Value	Reason
Oct-27-2020 18:11:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: Oct/27/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Oct-27-2020 18:11:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: 140.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Oct-27-2020 18:11:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Oct-27-2020 18:11:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: 63.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Oct-27-2020 18:11:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Oct-27-2020 18:11:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24.9	Initial Entry

7.a

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 16:04

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - 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

Date	Location	User	Value	Reason
Oct-27-2020 18:11:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: Record Identifier:: 1 Temperature: 98.1 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Oct-27-2020 18:11:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Oct-27-2020 18:11:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: 98.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Oct-27-2020 18:11:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Oct-27-2020 18:11:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-27-2020 18:12:01 (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
Oct-27-2020 18:12:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-27-2020 18:12:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: Oct/27/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Oct-27-2020 18:12:01 (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
Oct-27-2020 18:12:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-27-2020 18:12:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: NEGATIVE	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 10-Oct-2020 15:58

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

			Not Done::	
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6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-27-2020 18:12:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-27-2020 18:12:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-27-2020 18:12:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: NEGATIVE	Initial Entry

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: RANDOMIZATION - 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

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1. Randomization Date :

Date	Location	User	Value	Reason
Oct-29-2020 05:26:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Closed	DOV updated
Oct-28-2020 15:53:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Randomization date correct. DOV to be updated.
Oct-27-2020 18:11:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Randomization Date 27/Oct/2020 is before or more than 1 day after corresponding Date of Visit 13/Oct /2020. Please review and update as appropriate.
Oct-27-2020 18:11:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe.mgrimmnett)	Data Entry: Oct/27/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Oct-27-2020 18:11:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmnett)	Data Entry: 105602	Initial Entry

090177e196ae3d3f\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, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-27-2020 18:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-27-2020 18:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-28-2020 19:34:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Closed	Auto closed by Validation Check: VC_BEETRK001_04
Oct-28-2020 15:53:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 2: Answered	Date of collection correct. DOV to be updated.
Oct-28-2020 01:38:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Opened	DMW5202595;Date of Collection is earlier or more than 1 day after Date of Visit. Please clarify or correct.
Oct-27-2020 18:08:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 18:07:40 (UTC-07:00) Mountain Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e196ae3d3f\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: 10061176
 Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - 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

(US & Canada)				correct as appropriate.
Oct-27-2020 18:07:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimm (pfe mgrimm)	Data Entry: YES Date of Col lection: Oct/27/20 20	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 18:08:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimm)	Data Entry: Sample ID: BH244F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 18:08:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimm)	Data Entry: BH244F	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-27-2020 18:08:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimm)	Data Entry: Sample ID: BSJPKS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 18:08:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimm)	Data Entry: BSJPKS	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-27-2020 18:08:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimm)	Data Entry: Sample ID: BJ7MGL	Initial Entry

090177e196ae3d3f\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, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 18:08:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: BJ7MGL	Initial Entry

090177e196ae3d3f\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, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-27-2020 18:07:48 (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-27-2020 18:07:48 (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-29-2020 05:27:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe ks66)	Query 2: Closed	Response satisfies query
Oct-28-2020 15:53:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 2: Answered	DOV to be updated.
Oct-27-2020 18:09:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-27-2020 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection 27/Oct/2020 is more than 1 day after Date of Visit 13/Oct/2020. Please review and update as appropriate, else clarify.
Oct-27-2020 18:09:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmert (pfe mgrimmert)	Data Entry: YES Date of Collection: Oct/27/2020	Transcription Error
Oct-27-2020 18:07:48 (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

090177e196ae3d3f\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, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

				correct as appropriate.
Oct-27-2020 18:07:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: YES	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-27-2020 18:09:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: Sample ID: BH249Z	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-27-2020 18:09:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: BH249Z	Initial Entry

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: VACCINATION - 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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-13-2020 18:02:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: YES Date of First Delay: Oct/13/2020 Reason(s) for Temporary Delay of Vaccination RECENT NON-STUDY VACCINATION	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-27-2020 18:16:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-27-2020 18:16:04 (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
Oct-29-2020 05:47:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Closed	Response satisfies query
Oct-28-2020 15:54:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	DOV to be updated.
Oct-27-2020 18:16:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Dose Date is before or more than 1 day after Date of Visit 13/Oct/2020 of the corresponding Visit. Please review and

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - 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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

				update as appropriate.
Oct-27-2020 18:16:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmnett)	<u>Data Entry:</u> Oct/27/2020 17:59	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-27-2020 18:16:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-27-2020 18:16:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmnett)	<u>Data Entry:</u> LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-27-2020 18:16:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-27-2020 18:16:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED OBSE RVATION 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
Oct-27-2020 18:16:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmnett)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - 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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Oct-27-2020 18:12:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	Data Entry: NO - REACTOGENICITY E-DIAR Y NOT COLLECTED FOR THIS S UBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

Generated By: pfe.lewissc

Form: DATE OF VISIT - 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

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-24-2020 16:17:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Nov-24-2020 02:00:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Jayesh Yeole (pfe.yeolej)	Query 3: Opened	DM: Erroneous Visit is marked, but date of visit is entered. Please either, untick the erroneous visit button if visit occurred, or clear the data from rest of forms if entered in error and update accordingly or else clarify.
Nov-23-2020 15:05:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Nov-23-2020 15:05:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Nov/19/2020	Transcription Error
Nov-07-2020 02:16:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 2: Closed	Response satisfies query
Nov-06-2020 12:29:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 2: Answered	Form level comment changed to Not Applicable per DM request as it was previously requested to be NOT DONE.
Nov-05-2020	ACV0PFEINFP6000	Usha Ogirala	Query 2: Reopened	DM2: Please review

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: DATE OF VISIT - 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

02:45:08 (UTC-07:00) Mountain Time (US & Canada)		(pfe.ogirau)	ssued:Open ed	and add form level comment as Not Applicable on the forms of this visit or else clarify. Thank you.
Nov-04-2020 09:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 2: An swered	Changed data per query
Nov-04-2020 02:44:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Usha Ogirala (pfe.ogirau)	Query 2: Rei ssued:Open ed	DM1: As previous response confirms this visit is erroneous visit. Please add form level comment of NOT DONE in all the forms of this visit. Thank you.
Nov-03-2020 11:51:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 2: An swered	Unable to erase date entered in error for erroneous visit
Nov-02-2020 06:21:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 2: Op ened	DM: Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit. If not, consider to add 'Not Applicable' form level comment to rest of the forms.
Oct-29-2020 23:33:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Clo sed	Response satisfies query
Oct-29-2020 12:42:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: An swered	Date for V2 entered in error

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-29-2020 12:42:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-28-2020 23:31:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW5210936;The Date of Visit at Visit V2_VAX2_L is the same as the other Date of Visit at Visit V1_DAY1_VAX1_L. Please review for duplication and update as appropriate.
Oct-28-2020 16:28:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Oct/27/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Nov-24-2020 16:17:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry:	Transcription Error
Oct-29-2020 12:42:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: ERRONEOUS VISIT	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - 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

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1. Date:

Date	Location	User	Value	Reason
Nov-23-2020 15:06:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Nov/19/2020	Initial Entry
Nov-23-2020 15:06:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:27:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:03:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-23-2020 15:06:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Record Identifier:: Not Done Temperature: 97.7 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry
Nov-23-2020 15:06:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Record Identifier:: Not Done Temperature: Temperature Unit: Temperature Location::	Initial Entry
Nov-06-2020 12:27:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Record Identifier:: Not Done Temperature: Not Applicable Temperature Unit: Not Applicable Temperature Location: Not Applicable	Initial Entry
Nov-04-2020 09:03:25 (UTC-07:00) Mountain	ACV0PFEINFP6000	Lindsey Bevan	Data Entry: Record Identifier:: Not Done	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - 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

Time (US & Canada)		(pfe.lbevan)	Temperature: Not Done Temperature Unit: Not Done Temperature Location:: Not Done
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2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-04-2020 09:03:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-23-2020 15:06:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: 97.7	Initial Entry
Nov-23-2020 15:06:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:27:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:03:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-23-2020 15:06:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: F	Initial Entry
Nov-23-2020 15:06:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:27:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:03:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

2.a Temperature Location:

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - 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

Date	Location	User	Value	Reason
Nov-23-2020 15:06:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: ORAL CAVITY	Initial Entry
Nov-23-2020 15:06:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:27:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:03:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 15:58

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-23-2020 15:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry
Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Nov-23-2020 15:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry
Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-23-2020 15:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Nov/19/2020	Initial Entry
Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry

090177e196ae3d3f\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: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> Not Applicable	Initial Entry
Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> Not Done	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Nov-23-2020 15:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> STUDY SITE	Initial Entry
Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	<u>Data Entry:</u>	Initial Entry
Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> Not Applicable	Initial Entry
Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> Not Done	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Nov-23-2020 15:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> URINE	Initial Entry
Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	<u>Data Entry:</u>	Initial Entry
Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> Not Applicable	Initial Entry
Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Nov-23-2020 15:13:30 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 15:58

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - 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

Time (US & Canada)			Sponsor-Defined Identifier: 113 Test:: Not Done Result:: NEGATIVE Not Done::	
Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Sponsor-Defined Identifier: Test:: Not Done Result:: Not Done::	Initial Entry
Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Done Result:: Not Applicable Not Done:: Not Applicable	Initial Entry
Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-23-2020 15:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry
Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d3f\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: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry
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6.a Test:

Date	Location	User	Value	Reason
Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Nov-23-2020 15:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NEGATIVE	Initial Entry
Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Nov-23-2020 15:13:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:03:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

090177e196ae3d3f\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, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-23-2020 15:14:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry
Nov-23-2020 15:13:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Nov-03-2020 11:50:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Oct-28-2020 16:29:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-28-2020 16:28:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-23-2020 15:14:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry
Nov-23-2020 15:13:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry
Nov-03-2020 11:50:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Oct-28-2020 16:29:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Transcription Error
Oct-28-2020 16:28:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

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, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

Date	Location	User	Value	Reason
Nov-23-2020 15:15:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Deleted	Close Auto Query
Nov-23-2020 15:15:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-23-2020 15:14:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Nov-23-2020 15:14:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-23-2020 15:14:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES Date of Collection: Nov/19/2020	Initial Entry
Nov-23-2020 15:13:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-04-2020 09:54:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Christopher Lewis (pfe.lewisc45)	Query 3: Closed	Response satisfies query
Nov-03-2020 11:50:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 3: Answered	Changed data per query
Nov-03-2020 11:50:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-02-2020 14:13:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Christopher Lewis (pfe.lewisc45)	Query 3: Opened	Please enter a form level comment indicating N/A until this visit occurs.
Oct-28-2020 16:29:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query

090177e196ae3d3f\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, Frozen, Verified
Site No: 1006
Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061176
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:04

Oct-28-2020 16:29:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry:	Transcription Error
Oct-28-2020 16:29:12 (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.
Oct-28-2020 16:28:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-28-2020 16:28:28 (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-28-2020 16:28:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES Date of Collection: Oct/27/2020	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 15:13:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-03-2020 11:50:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-23-2020 15:15:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Sample ID: BH24BB	Initial Entry
Oct-28-2020 16:29:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID:	Transcription Error
Oct-28-2020 16:28:38 (UTC-07:00) Mountain	ACV0PFEINFP6000	Lindsey Bevan	Data Entry: Sample ID: BH249Z	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, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)		(pfe.lbevan)		
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5.a Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 15:15:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	<u>Data Entry:</u> BH24BB	Initial Entry
Oct-28-2020 16:29:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u>	Transcription Error
Oct-28-2020 16:28:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> BH249Z	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-23-2020 15:15:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	<u>Data Entry:</u> <u>Sample ID:</u>	Transcription Error
Nov-23-2020 15:14:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	<u>Data Entry:</u> <u>Sample ID:</u> BH24BB	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-23-2020 15:15:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	<u>Data Entry:</u>	Transcription Error
Nov-23-2020 15:14:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	<u>Data Entry:</u> BH24BB	Initial Entry

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: VACCINATION - 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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-23-2020 15:16:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry
Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-23-2020 15:16:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry
Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-23-2020 15:16:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry
Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - 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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-23-2020 15:16:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Nov/19/2020 17:41	Initial Entry
Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-23-2020 15:16:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry
Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-23-2020 15:16:08 (UTC-07:00) Mountain	ACV0PFEINFP6000	Bradley Young	Data Entry: LEFT	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - 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: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

Time (US & Canada)		(pfe.byoung)		
Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Nov-23-2020 15:16:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry
Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
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090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - 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: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-23-2020 15:16:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD	Initial Entry
Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

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

Date	Location	User	Value	Reason
Nov-23-2020 15:16:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES	Initial Entry
Nov-23-2020 15:15:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Initial Entry
Nov-06-2020 12:28:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Applicable	Initial Entry
Nov-04-2020 09:04:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

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I. Date of Visit

Date	Location	User	Value	Reason
Jan-19-2021 00:29:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kiran Potdar (pfe.potdak02)	Query 2: Clo sed	Per site confirmation_Updated PD tracker
Jan-18-2021 17:34:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Query 2: Ans wered	date correct as entered, will report this pd
Jan-17-2021 23:25:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 2: Op ened	PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 5 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. "[naikp09 SDQ=91629]"
Dec-30-2020 23:55:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 1: Clo sed	Response satisfies query
Dec-30-2020 10:27:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Ans wered	Changed data per query
Dec-30-2020 04:27:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Op ened	DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of visit at visit 3.

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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: DATE OF VISIT - 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

Dec-29-2020 12:44:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Heather Littell (pfe.hlittell)	Data Entry : Dec/2 9/202 0	Initial Entry
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090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
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: 10061176 **Subject Initials:** ---
Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:04

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1. Data Origin

Date	Location	User	Value	Reason
Dec-29-2020 12:44:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-29-2020 12:44:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-30-2020 10:27:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-30-2020 00:00:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-29-2020 12:44:30 (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.
Dec-29-2020 12:44:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Heather Littell (pfe.hlittell)	Data Entry: YES Date of Collection: Dec/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-30-2020 10:27:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BRL0TR	Initial Entry

090177e196ae3d3f\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, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 10:27:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BRL0TR	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-30-2020 10:27:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BJ7MP8	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 10:27:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BJ7MP8	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-30-2020 10:27:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BJ7ML8	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-30-2020 10:27:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BJ7ML8	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 Form: DATE OF VISIT - ILLNESS ONSET - 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: 10061176

Subject Initials: ---

Generated By: pfe.levissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-25-2021 03:26:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 3: Closed	Response satisfies query
Feb-24-2021 11:18:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 3: Answered	Changed data per query
Feb-22-2021 06:59:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 3: Opened	DM: Kindly consider to update missing HOSPITALIZATION DETAILS form or else clarify. Thank you.
Nov-11-2020 16:11:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-11-2020 16:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-11-2020 16:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	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.
Nov-11-2020 16:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Nov/11/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
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090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** DATE OF VISIT - ILLNESS ONSET - 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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-11-2020 16:10:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry
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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020**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:** 10061176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Nov/11/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Nov/10/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Dec-16-2020 11:50:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO Date of Last Symptom Resolved: Nov/20/2020	New Information
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (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
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry
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4.b

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: NEW OR INCREASE D COUGH Symptom Pr YES esent:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (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
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptom NEW OR INCREASED S s: HORTNESS OF BREATH Symptom NO Present:	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (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
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (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
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020**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:** 10061176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04**4.e Symptoms:**

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (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
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NEW OR INCREASED SORE THRO AT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: DIARRHEA Symptom Present: YES	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (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
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-11-2020 16:10:39 (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
Nov-11-2020 16:10:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-11-2020 16:10:49 (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
Nov-11-2020 16:10:49 (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
Nov-11-2020 16:10:49 (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
Nov-11-2020 16:10:49 (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
Nov-11-2020 16:10:49 (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
Nov-11-2020 16:10:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

7. Test Result:

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Nov-11-2020 16:10:49 (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
Nov-11-2020 16:10:49 (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
Nov-11-2020 16:10:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Not Done	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061176**Generated By:** pfe.levisse**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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. Data Origin**

Date	Location	User	Value	Reason
Nov-11-2020 16:11:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-11-2020 16:11:02 (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
Nov-12-2020 14:50:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-11-2020 18:21:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Opened	Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-11-2020 16:11:02 (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.
Nov-11-2020 16:11:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES Date of Collection: Nov/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-12-2020 14:50:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe.mgrimmnett)	Data Entry: Sample ID: CV49749	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Nov-12-2020 14:50:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Megan Grimmett (pfe mgrimmett)	<u>Data Entry:</u> CV49749	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Nov-11-2020 16:11:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-11-2020 16:11:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-11-2020 16:11:13 (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
Nov-11-2020 16:11:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Telehealth visit	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Not Complete

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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I.a

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or C NO ontacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (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
Nov-11-2020 16:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Type of Practitioner: EMERGENC Y ROOM Occurrence of Visits NO or Contacts:	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Not Complete**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (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
Nov-11-2020 16:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

I.c

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (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: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (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
Nov-11-2020 16:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (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

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Not Complete**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Type of Practitioner: TELEPHONE C ONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (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
Nov-11-2020 16:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Type of Practitioner: OTHE R Occurrence of Visits or Contacts: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Not Complete

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-11-2020 16:11:35 (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
Nov-11-2020 16:11:35 (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
Mar-11-2021 19:35:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 2: Closed	Response satisfies query
Mar-11-2021 10:38:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-11-2021 10:38:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Transcription Error
Mar-10-2021 06:29:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 2: Opened	Clin: Please hospitalization data entered on COVID_A HEALTH CARE UTILIZATION CRF form should be removed since they are already correctly captured on COVID_B HEALTH CARE UTILIZATION CRF form
Mar-09-2021 06:26:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Closed	Response satisfies query
Mar-08-2021 13:44:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	All vital signs available have been reported

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Header Text: c4591001 Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History Form Version: 10-Oct-2020 15:59 Form Status: Data Complete, Not Complete Site No: 1006 Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic Subject No: 10061176 Subject Initials: --- Generated By: pfe.levisse Generated Time (GMT): 29-Mar-2021 04:04				
Mar-04-2021 12:27:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Reissued:Opened	CLINQUERY: Please enter on the relevant CRF form any available info (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain this information.
Mar-04-2021 10:17:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-04-2021 10:17:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? NO	Transcription Error
Mar-02-2021 06:09:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Reissued:Opened	[DM - unfreeze Health Care Utilization CRF] CLINQUERY:Per HOSP CRF, subject hospitalized. Please confirm. Please enter on the relevant CRF form any available info (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...).
Mar-01-2021 12:49:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Reissued:Candidate	[DM - unfreeze Health Care Utilization CRF] CLINQUERY:Per HOSP CRF, subject hospitalized. Please confirm. Please enter on the relevant CRF form any available info (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...).
Feb-26-2021 09:10:39 (UTC-07:00) Mountain	ACV0PFEINFP6000	Lindsey Bevan	Query 1: Answered	Confirm hospital stay. Please unfreeze the

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Not Complete

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.lévissc

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

Time (US & Canada)		(pfe.lbevan)		Health Care Utilization crf. All other crfs correct
Feb-25-2021 15:30:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Opened	CLINQUERY: Per HOSP CRF, subject hospitalized. Please confirm. Please enter on the relevant CRF form any available info (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain this information.
Nov-11-2020 16:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** HOSPITALIZATION DETAILS - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

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Date	Location	User	Value	Reason
Mar-11-2021 11:24:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Deleted	Captured at COVID Convalescent B1
Feb-24-2021 11:17:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 Form: HOSPITALIZATION DETAILS - 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: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

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

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Feb-24-2021 11:17:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Mar-11-2021 19:35:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Closed	Response satisfies query
Mar-11-2021 11:24:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Captured at COVID Convalescent B1
Mar-10-2021 06:27:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Reissued:Opened	Clin: Please hospitalization data entered on COVID_A HOSPITALIZATION DETAILS CRF form should be removed since they are already correctly captured on COVID_B HOSPITALIZATION DETAILS CRF form
Mar-09-2021 11:43:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Dates entered correctly with COVID_B
Mar-08-2021 15:42:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 1: Opened	Clin: This hospitalization is already entered on the potential COVID_B Visit. Please review and confirm if this hospitalization should be capture on COVID_A visit despite the start/end date of this hospitalizing do not correspond to COVID_A but to

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** HOSPITALIZATION DETAILS - 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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

				COVID_B
Feb-24-2021 11:17:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Feb-24-2021 11:17:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Feb/8/2021	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Feb-24-2021 11:17:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO Discharge Date: Feb/10/2021	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-11-2020 16:11:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-11-2020 16:11:45 (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
Nov-11-2020 16:11:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: 1	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** VITAL SIGNS - COVID - Audit Trail

Form Version: 10-Oct-2020 15:59

Form Status:

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Feb-17-2021 11:22:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 Form: VITAL SIGNS - COVID - eCRF Audit Trail History

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date:

Date	Location	User	Value	Reason
Feb-17-2021 11:22:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Feb/8/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-17-2021 11:22:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Record Identifier:: 1 Systolic:: 10 5 Diastolic:: 67 Respiratory Rate in respirations /minute: 22 Heart Rate in beats/minute: 13 3	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-17-2021 11:22:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Feb-17-2021 11:22:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: 105	Initial Entry

2.a Diastolic:

Date	Location	User	Value	Reason
Feb-17-2021 11:22:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: 67	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
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090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Feb-17-2021 11:22:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: 22	Initial Entry
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2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Feb-18-2021 14:41:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Feb-18-2021 11:36:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Not clinically significant per PI
Feb-17-2021 22:39:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Reissued:Opened	DM: Please confirm reported Heart rate is not clinically significant. If yes, please update AE. Thank you.
Feb-17-2021 11:22:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Original value is correct
Feb-17-2021 11:22:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Heart rate 133 is outside of Normal Range 0 - 120.
Feb-17-2021 11:22:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: 133	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail

Form Version: 10-Oct-2020 16:04

Form Status:

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Feb-17-2021 11:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Created	

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/11/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date:

Date	Location	User	Value	Reason
Feb-17-2021 11:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Feb/8/2021	Initial Entry

2.a

Date	Location	User	Value	Reason
Feb-17-2021 11:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 91.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-17-2021 11:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Feb-17-2021 11:23:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: 91.0	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** DATE OF VISIT - ILLNESS ONSET - 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:** 10061176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-10-2021 17:21:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Feb-10-2021 17:19:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-10-2021 17:19:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	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.
Feb-10-2021 17:19:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Feb/10/2021	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Feb-10-2021 17:19:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_B	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Feb/10/2021	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Feb/3/2021	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

4.b

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES	Initial Entry

4.d

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom Present: NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
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Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021
Form Version: 14-Jan-2021 02:23
Site No: 1006
Subject No: 10061176
Generated By: pfe.levisse

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

Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Symptoms: NEW LOSS OF TAST E OR SMELL Symptom P NO resent:	Initial Entry
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4.f Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom YES Present:	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NEW OR INCREASED SORE THRO AT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES	Initial Entry

4.h

Date	Location	User	Value	Reason
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Header Text: c4591001
Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
Form Version: 14-Jan-2021 02:23 **Form Status:** Data Complete, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061176 **Subject Initials:** ---
Generated By: pfe.leivissc **Generated Time (GMT):** 29-Mar-2021 04:04

Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry
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4.h Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-10-2021 17:20:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** MICROBIOLOGY SPECIMEN - Audit Trail

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Feb-10-2021 17:21:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Form Created	

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**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:** 10061176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Feb-10-2021 17:21:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Feb/8/2021	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Feb-10-2021 17:21:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Feb-10-2021 17:21:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Feb-10-2021 17:21:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Feb-10-2021 17:21:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Feb-10-2021 17:21:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-10-2021 17:21:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Trade Name is Other, however Trade Name Other, Specify is not

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

				completed. Please update.
Feb-10-2021 17:21:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Feb-10-2021 17:21:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NEGATIVE	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Feb-10-2021 17:21:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry:	Transcription Error
Feb-10-2021 17:21:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: clia certified	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Feb-10-2021 17:21:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: clia certified	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - 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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-10-2021 17:21:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-10-2021 17:21:47 (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
Feb-11-2021 14:26:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-11-2021 04:29:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nair29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-10-2021 17:21:47 (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.
Feb-10-2021 17:21:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES Date of Collection: Feb/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-11-2021 14:26:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: CV46529	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

5.a Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 14:26:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> CV46529	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-10-2021 17:22:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-10-2021 17:22:05 (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
Feb-10-2021 17:22:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	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
Feb-10-2021 17:22:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: self swab	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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I.a

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Type of Practitioner: SPECIAL IST Occurrence of Visits or Contacts: NO	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

I.b

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Type of Practitioner: EMERGENCY R OOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04***I.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.c

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

I.d

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Type of Practitioner: URGENT CARE	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

			Occurrence of Visits or NO Contacts:	
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I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

I.f

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young	Data Entry: Type of Practitioner: OTHE	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)		(pfe.byoung)	R	
Occurrence of Visits or Contacts:				

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-18-2021 11:58:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Closed	Response satisfies query
Feb-18-2021 11:26:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	All data related to hospitalization has been entered. No imaging.
Feb-15-2021 11:44:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Vrunda Parikh (pfe.parikv06)	Query 1: Opened	CLINQUERY: Subject was hospitalized. Please enter on the relevant CRF form any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain this information.
Feb-10-2021 17:22:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

			s?	
			NO	

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** HOSPITALIZATION DETAILS - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Feb-10-2021 17:22:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 **Form:** HOSPITALIZATION DETAILS - 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: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Feb-10-2021 17:22:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Feb/8/2021	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Feb-10-2021 17:22:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO Discharge Date: Feb/10/2021	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit on Feb/10/2021 Form: ILLNESS DETAILS - eCRF Audit Trail History

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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-10-2021 17:23:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Feb-10-2021 17:23:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> strep throat Date of Diagnosis: Feb/8/2021	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-10-2021 17:23:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: 3	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail on Dec/11/2020
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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-21-2021 09:24:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Dec/11/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Jan-21-2021 09:24:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: COVID_A1	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit
on Dec/11/2020**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:** 10061176**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Jan-21-2021 09:24:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-21-2021 09:24:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-21-2021 09:24:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 09:24:43 (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.
Jan-21-2021 09:24:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES Date of Collection: Dec/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-21-2021 09:24:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BCSY13	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 09:24:55 (UTC-07:00) Mountain	ACV0PFEINFP6000	Lindsey Bevan	Data Entry: BCSY13	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Dec/11/2020 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: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

Time (US & Canada)		(pfe.lbevan)		
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5.b

Date	Location	User	Value	Reason
Feb-22-2021 11:38:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Sample ID: BS8WJ3	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 11:38:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: BS8WJ3	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-22-2021 11:38:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Sample ID: BS8WJY	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-22-2021 11:38:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: BS8WJY	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

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

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Date	Location	User	Value	Reason
Feb-10-2021 17:26:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - 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

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1. Category:

Date	Location	User	Value	Reason
Feb-10-2021 17:26:35 (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
Feb-10-2021 17:26:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-05-2021 17:38:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Query closed; will follow for requested citalopram indication information.
Mar-04-2021 10:29:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Safety database to be updated
Feb-28-2021 18:13:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical - Followup; in current SAE update (15Feb21) the indication for citalopram remains Depression
Feb-17-2021 11:13:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Safety database to be updated
Feb-16-2021 16:25:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Feb-15-2021 14:10:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Please submit a SAE safety update with presenting symptoms and treatment for SAE of asthma exacerbation

090177e196ae3d3f\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: 10061176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Feb-15-2021 12:07:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical SAE Med history states Anxiety (not depression); SAE concomitant medications reports Citalopram for Depression (not anxiety). Please clarify and report all med Hx conditions that medication is being received for (including also migraine)
Feb-10-2021 17:26:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Acute Asthma Exacerbation	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-10-2021 17:26:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Feb/3/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 11:24:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Deleted	Transcription Error
Feb-18-2021 11:24:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO End Date Time: Feb/10/2021 UNK:UNK	Transcription Error
Feb-16-2021 12:05:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Christopher Lewis (pfe.lewisc45)	Query 1: Candidate	Please confirm if Acute asthma exacerbation resolved on 10Feb2020 upon discharge as subject returned to baseline of strep.
Feb-10-2021 17:26:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES	Initial Entry

090177e196ae3d3f\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, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-10-2021 17:26:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	<u>Data Entry:</u> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Mar-04-2021 06:22:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Closed	COVID test (neg) specified on 03Feb21
Feb-28-2021 18:13:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Reissued:Opened	Clinical - Followup; in most recent SAE update (15Feb21), no dates are specified for 2 COVID tests
Feb-17-2021 11:14:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 3: Answered	Safety database to be updated with new information
Feb-16-2021 16:30:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 3: Opened	Clinical - SAE report (#2021148838) reports 2 negative COVID tests; however, there are no dates for the tests. Does one of these represent an outpt test on 03Feb21? Please submit a SAE update specifying the test dates in lab test section
Feb-16-2021 16:28:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	rewording
Feb-16-2021 01:39:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Feb-15-2021 12:08:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical - SAE report (#2021148838) reports 2 negative COVID tests in hospital; however, there are no dates for the tests. Please submit a SAE update with the test dates (& was 1 a rapid test).
Feb-10-2021 17:26:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Acute Asthma Exacerbation: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-10-2021 17:26:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth 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>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p>	Initial Entry

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Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1006
Subject No: 10061176
Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

NO

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

Date	Location	User	Value	Reason
Feb-10-2021 17:26:35 (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
Feb-18-2021 00:01:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Feb-17-2021 11:14:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Safety Database updated on 2/15/21
Feb-17-2021 00:48:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2021148838 .causality was recorded as NO DATA in Safety database but was recorded as NOT RELATED in AE CRF. Please confirm correct causality. If safety update is required, please submit a follow-up form.
Feb-10-2021 17:26:35 (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 <i>If Other, specify:</i> strep pharyngitis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-10-2021 17:26:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NOT APPLICABLE	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - 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

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-03-2021 08:22:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Feb-17-2021 13:14:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	Response satisfies query
Feb-17-2021 11:15:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 2: Answered	Changed data per query
Feb-17-2021 11:15:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Prohibited Conmed eCRF updated
Feb-16-2021 16:26:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical SAE report (2021148838) states subject received Prednisone for SAE of Asthma exacerbation. Please review dose and duration per protocol; if required please complete Prohibited Con Med log
Feb-12-2021 09:52:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	clinical: pls advise if systemic steroids were given, and if so, what was the dose and duration. Thanks
Feb-10-2021 17:26:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-10-2021 17:26:35 (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
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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061176

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - 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

Feb-18-2021 14:46:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Feb-18-2021 11:23:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-18-2021 11:23:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: RECOVERED/RESOLVED	Transcription Error
Feb-18-2021 00:00:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2021148838,outcome was reported as RECOVERED/RESOLVED to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-10-2021 17:26:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: RECOVERING/RESOLVING	Initial Entry

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

Date	Location	User	Value	Reason
Feb-10-2021 17:26:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-16-2021 01:39:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2021148838	Initial Entry

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Header Text: c4591001
Visit: Logs - Unscheduled **Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail
Form Version: 22-Apr-2020 21:03 **Form Status:**
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061176 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

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Date	Location	User	Value	Reason
Oct-13-2020 18:02:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-13-2020 18:02:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-13-2020 18:02:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-13-2020 18:02:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Oct-13-2020 18:02:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Influenza Vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-13-2020 18:02:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Oct/10/2020	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061176

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED - 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 ***

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Date	Location	User	Value	Reason
Feb-24-2021 11:19:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Deleted	Not capturable as treatment course was not >= 14 days
Feb-17-2021 10:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Created	

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-17-2021 10:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-24-2021 15:57:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 2: Closed	Response satisfies query
Feb-24-2021 11:19:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Not capturable as treatment course was not >= 14 days
Feb-18-2021 17:47:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lisa McLeod (pfe.mcleol03)	Query 2: Opened	GPD Clin: Although patient received >=20mg/day of systemic corticosteroids, treatment course was not >=14 days. please confirm if entry has been captured in error.
Feb-18-2021 12:04:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Christopher Lewis (pfe.lewisc45)	Query 1: Closed	Response satisfies query
Feb-17-2021 10:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-17-2021 10:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: CORTICOSTEROIDS	Initial Entry
Feb-16-2021 12:01:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Christopher Lewis (pfe.lewisc45)	Query 1: Opened	Please confirm if Prednisone regime should be captured here.

3. Concomitant Medications Pre-specified:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

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Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

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

Date	Location	User	Value	Reason
Feb-17-2021 10:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> NO	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Feb-17-2021 10:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> Prednisone	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Feb-17-2021 10:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> 30	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Feb-17-2021 10:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> mg	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Feb-17-2021 10:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> BID	Initial Entry

8. Route:

Date	Location	User	Value	Reason
Feb-17-2021 10:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> ORAL	Initial Entry

9. Start Date:

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Feb-17-2021 10:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Feb/6/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Feb-17-2021 14:46:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: NO End Date: Feb/14/2021	New Information
Feb-17-2021 10:56:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 10-Dec-2020 02:29

Site No: 1006

Subject No: 10061176

Generated By: pfe.lewissc

Form: DISPOSITION - TREATMENT - 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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-30-2020 10:26:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Dec/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-30-2020 10:26:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-30-2020 10:26:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d3f\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: 10061176

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-26-2021 10:07:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Jan/28/2021	Transcription Error
Feb-03-2021 13:21:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Feb/3/2021	Initial Entry

090177e196ae3d3f\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061176

Subject Initials: ---

Generated By: pfe.levisse

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

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

Date	Location	User	Value	Reason
Feb-03-2021 13:21:41 (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 per local/national recommendations and 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: 10061176

Generated By: pfe.lewissc

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-03-2021 13:21:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Feb/3/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-03-2021 13:21:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: ASSESS ELIGIBILITY FOR ADDITI ONAL VACCINATION	Initial Entry

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Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061176

Generated By: pfe.lewissc

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

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1. Subject Status

Date	Location	User	Value	Reason
Dec-30-2020 10:26:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Oct-27-2020 18:11:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Oct-13-2020 18:02:04 (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
Dec-30-2020 10:26:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/29/2020	Initial Entry
Oct-27-2020 18:11:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/27/2020	Initial Entry
Oct-13-2020 18:02:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/13/2020	Initial Entry

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