

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/24/2020
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Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10061098]
2.	Birth Date:	(b) (6)/1954
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:	

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.lewissc

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/24/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Premarin Allergy (Hives)]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Macrodantin Allergy (Hives)]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Recurrent Muscle Spasms (Whole Body)]
	Start Date:	Mar/10/2017
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Attention Deficit Hyperactivity Disorder]
	Start Date:	Feb/1/1989
	Ongoing:	YES

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma (Moderate)]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Migraines with Aura]
	Start Date:	UNK/UNK/1979
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Recurrent Sinusitis]
	Start Date:	UNK/UNK/1980
	Ongoing:	NO End Date: UNK/UNK/2017
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gastrointestinal Bleed]
	Start Date:	Nov/27/2017
	Ongoing:	NO End Date: Dec/UNK/2017

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tinnitus Left Ear]
	Start Date:	Mar/12/2015
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Lumbar Disc Degeneration]
	Start Date:	Aug/14/2014
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Mild Anxiety]
	Start Date:	May/19/2014
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Insomnia]
	Start Date:	Sep/13/2013
	Ongoing:	YES

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Chronic Fatigue Syndrome]
	Start Date:	Aug/14/2012
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoporosis]
	Start Date:	Feb/UNK/2020
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Rosacea (mild)]
	Start Date:	Sep/12/2011
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Complete Hysterectomy]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: UNK/UNK/1989

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Post Partum Hemorrhage]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: UNK/UNK/1989
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Postmenopausal]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Urethral Sling]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bilateral Eye Cataracts]
	Start Date:	Oct/20/2016
	Ongoing:	NO End Date: Feb/16/2017

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Basal Cell Carcinoma (Forehead)]
	Start Date:	Sep/11/2011
	Ongoing:	NO End Date: Sep/11/2011
1.v	Line/MH Number:	[22]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[History of Recurrent Actinic Keratosis]
	Start Date:	Sep/6/2011
	Ongoing:	YES
1.w	Line/MH Number:	[23]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Restless Leg Syndrome]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.x	Line/MH Number:	[24]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Postural Orthostatic Tachycardia Syndrome]
	Start Date:	UNK/UNK/1966
	Ongoing:	YES

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.y	Line/MH Number:	[25]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Ehlers-Danlos Syndrome]
	Start Date:	UNK/UNK/1966
	Ongoing:	YES
1.z	Line/MH Number:	[26]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Recurrent Urinary Tract Infection]
	Start Date:	UNK/UNK/1974
	Ongoing:	YES
1.aa	Line/MH Number:	[27]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Environmental Allergies]
	Start Date:	UNK/UNK/1969
	Ongoing:	YES

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/24/2020
2.	Weight:	[133.2]
3.	Unit:	LB
4.	Height:	[65.75]
5.	Unit:	in
6.	Body Mass Index:	[21.7]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[98.3]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

6.a	Sponsor ID:	Not Applicable _____ []	Comments
	Test:	Not Applicable _____ Choriogonadotropin Beta_PX113	
	Result:	Not Applicable _____	Comments
	Not Done:	Not Applicable _____	Comments

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levissc

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Aug/24/2020
2.	Randomization Number:	[236124]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

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: Aug/24/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHV2YP]
5.b	Sample ID	[BHV2YR]
5.c	Sample ID	[BHV2YS]
5.d	Sample ID	[BJ7LYK]
5.e	Sample ID	[BJ7LYL]

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHV2PZ]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/24/2020 13:34
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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1006

Subject No: 10061098

Generated By: pfe.levissc

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VITAL SIGNS - TEMP

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/15/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[98.4]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061098

Generated By: pfe.levissc

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Lab Urinalysis

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

Lab Result

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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BCT8JS]
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Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/15/2020 15:51
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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
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	[BCT8F3]
5.b	Sample ID	[BJ7M8J]
5.c	Sample ID	[BJ7MFK]

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/9/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/9/2021
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	[BS8WTV]
5.b	Sample ID	[BS8WP2]
5.c	Sample ID	[BRBMF5]

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

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: 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: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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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090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L

Form: 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: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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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090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

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 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

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: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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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090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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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090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

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: 10061098

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 Illness Visit

3.	COVID-19 Illness Visit:	
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Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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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090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

Unplanned Assessments

1.	Assessments	
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090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/19/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB -
New Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

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

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: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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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090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

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: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Headache	Aug/24/2020 14:30	NO End Date Time: Aug/25/2020 07:00	Repeating Pages
2.	ADVERSE EVENT	2	ATRIAL FIBRILLATION INTERMITTENT	Oct/6/2020 UNK:UNK	NO End Date Time: Oct/12/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	URINARY TRACT INFECTION	Oct/3/2020 UNK:UNK	NO End Date Time: Oct/12/2020 UNK:UNK	Repeating Pages

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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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)	[Headache]
4.	Start Date Time:	Aug/24/2020 14:30
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/25/2020 07:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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	[]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[ATRIAL FIBRILLATION INTERMITTENT]
4.	Start Date Time:	Oct/6/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/12/2020 UNK:UNK
6.	Toxicity Grade:	2

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061098**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

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? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES	
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: CONCOMITANT DRUG TREATMENT	Comments
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	YES	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020405640]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[URINARY TRACT INFECTION]
4.	Start Date Time:	Oct/3/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/12/2020 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).	NO

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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: [BACTERIAL INFECTION]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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	[]

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1006

Subject No: 10061098

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	[]

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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/2/2020	Repeating Pages

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

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Concomitant Medications

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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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: 10061098

Generated By: pfe.levisse

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Radiation Treatment

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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

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: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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: 10061098

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:	

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

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:	

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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?	

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination -
Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

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: 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: 10061098

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: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

Informed Consent - Asymptomatic Surveillance

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT -
Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

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	Jan/18/2021
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: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

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 :	Jan/25/2021
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: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/19/2020

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisc

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: 30-Jul-2020 21:29
Site No: 1006
Subject No: 10061098
Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 04:04

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-25-2020 09:05:42 (UTC-07:00) Mountain Time (US & Canada)	Ty Henry (pfe.thenry)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	Ty Henry (pfe.thenry)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	Ty Henry (pfe.thenry)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	Ty Henry (pfe.thenry)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	Ty Henry (pfe.thenry)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	Ty Henry (pfe.thenry)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	Ty Henry (pfe.thenry)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	Ty Henry (pfe.thenry)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	Ty Henry (pfe.thenry)	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
6.a	Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	Ty Henry (pfe.thenry)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
9	Oct-21-2020 09:35:27 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	CIPROFLOXACIN

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisc

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

[Back to Form](#)

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

- CRF_Sign
- CRF_Sign_1

Name	Signature Meaning	Date	Type	Action
Ashley Bragg	N/A	Mar-09-2021 17:10:11 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

James Peterson	Approved	Mar-08-2021 15:51:47 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
----------------	----------	---	------	--------

Affidavit:

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

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

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

Bradley Young	N/A	Feb-26-2021 08:18:39 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
---------------	-----	---	--	-----------------------------------

Affidavit:
N/A

James Peterson	Approved	Jan-26-2021 21:29:37 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
----------------	----------	---	------	--------

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisc

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

Affidavit:

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

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

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

Lindsey Bevan	N/A	Jan-25-2021 13:38:04 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
---------------	-----	---	--	-----------------------------------

Affidavit:

N/A

James Peterson	Approved	Oct-30-2020 14:11:54 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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Affidavit:

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

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

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

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-25-2020 09:04:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:04:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

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I. Consent Was:

Date	Location	User	Value	Reason
Aug-25-2020 09:04:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: OBTAINED Date Written Consent Obtained Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Subject ID

Date	Location	User	Value	Reason
Aug-25-2020 09:04:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10061098	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:03:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1954	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-25-2020 09:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-25-2020 09:04:50 (UTC-07:00) Mountain Time (US	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NOT HISPANIC OR LATI NO(A) OR OF SPANISH ORIGIN	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001
Visit: COHORT_SELECTION **Form:** DEMOGRAPHY - eCRF Audit Trail History
Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:04

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

Date	Location	User	Value	Reason
Aug-25-2020 09:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Aug-25-2020 09:05:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-25-2020 09:06:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Aug/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-25-2020 09:06:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-25-2020 09:06:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061098**Subject Initials:** ---**Generated By:** pfe.lewissc**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)***1.a***

Date	Location	User	Value	Reason
Aug-25-2020 09:10:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: Premarin Allergy (Hives) Start Date: UNK/UNK/1989 Ongoing: YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:10:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:10:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Premarin Allergy (Hives)	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
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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, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

Aug-25-2020 09:10:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: UNK/UNK/1989	Initial Entry
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1.a Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:10:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-25-2020 09:11:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 2 umber: Medical Hi Macrochantin story Term: Allergy (Hive s) Start Date: UNK/UNK/19 90 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:11:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:11:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Macrochantin Allergy (Hives)	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:11:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: UNK/UNK/1990	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:11:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

I.c

Date	Location	User	Value	Reason
Aug-25-2020 09:12:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 3 Number: Medical History Recurrent Muscl Term: e Spasms (Whol e Body) Start Date: Mar/10/2017 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:12:07 (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-30-2020 07:40:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Oct-29-2020 12:53:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	No diagnosis assigned by any provider
Oct-27-2020 01:39:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Reissued:Open	GPDCLIN: please clarify if there is a known diagnosis/underlying condition that can be added to medical history. thank you
Oct-26-2020 17:33:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Confirmed "whole body" in source documentation.

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-24-2020 22:03:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Samuel Dychter (pfe.dychts)	Query 1: Opened	GPD Clin: Please clarify if the subject has a diagnosis that relates to the whole body muscle spasms.
Aug-25-2020 09:12:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Recurrent Muscle Spasms (Whole Body)	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:12:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Mar/10/2017	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:12:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-25-2020 09:12:57	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 4	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

(UTC-07:00)
Mountain Time (US
& Canada)

Number:
Medical History Term: Attention Deficit Hyperactivity Disorder
Start Date: Feb/1/1989
Ongoing: YES

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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:12:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 12:56:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-23-2020 13:42:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Changed data per query
Oct-23-2020 09:37:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL - SAE Med Hx reports subject has postural orthostatic tachycardia syndrome (no date of onset). Please review for clinical relevance to safety, and add this Med hx to

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

				CRF if appropriate (with onset date if available)
Aug-25-2020 09:12:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Attention Deficit Hyperactivity Disorder	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:12:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Feb/1/1989	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:12:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-25-2020 09:13:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5	Initial Entry

090177e196ae3d2\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

& Canada)			Medical History Term: Asthma (Moderate) Start Date: UNK/UNK/1985 Ongoing: YES	
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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, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:04

I.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:13:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:13:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Asthma (Moderate)	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:13:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: UNK/UNK/1985	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:13:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

If

Date	Location	User	Value	Reason
Aug-25-2020 09:14:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: Migraines with Aura Start Date: UNK/UNK/1979 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

1.f Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:14:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:14:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Migraines with Aura	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:14:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: UNK/UNK/1979	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:14:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

I.g

Date	Location	User	Value	Reason
Aug-25-2020 09:15:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Recurrent Sinusitis Start Date: UNK/UNK/1980 Ongoing: NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

I.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:15:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:15:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Recurrent Sinusitis	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:15:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: UNK/UNK/1980	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:15:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NO End Date: UNK/UNK/2017	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

1.h

Date	Location	User	Value	Reason
Aug-25-2020 09:16:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 8 mber: Medical Hist Gastrointesti ory Term: nal Bleed Start Date: Nov/27/2017 Ongoing: NO End Date: Dec/UNK /2017	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:16:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:16:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Gastrointestinal Bleed	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:16:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Nov/27/2017	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:16:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NO End Date: Dec/UNK/2017	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

Li

Date	Location	User	Value	Reason
Aug-25-2020 09:17:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 9 ber: Medical History Term: Tinnitus L left Ear Start Date: Mar/12/20 15 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

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1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:17:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:17:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Tinnitus Left Ear	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:17:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Mar/12/2015	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:17:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

& Canada)				
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I,j

Date	Location	User	Value	Reason
Aug-25-2020 09:18:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 10 umber: Medical His Lumbar Disc tory Term: Degeneration Start Date: Aug/14/2014 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:18:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:18:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Lumbar Disc Degeneration	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:18:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Aug/14/2014	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:18:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

l.k

Date	Location	User	Value	Reason
Aug-25-2020 09:19:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 11 er: Medical History Mild Anx Term: iety Start Date: May/19/2 014 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:19:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:19:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Mild Anxiety	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:19:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: May/19/2014	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:19:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

1.1

Date	Location	User	Value	Reason
Aug-25-2020 09:20:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: Insomnia Start Date: Sep/13/2013 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:20:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:20:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Insomnia	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:20:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Sep/13/2013	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:20:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

I.m

Date	Location	User	Value	Reason
Aug-25-2020 09:20:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH N 13 umber: Medical His Chronic Fatig tory Term: ue Syndrome Start Date: Aug/14/2012 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

1.m Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:20:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:20:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Chronic Fatigue Syndrome	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:20:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Aug/14/2012	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:20:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

I.n

Date	Location	User	Value	Reason
Aug-25-2020 09:21:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 14 ber: Medical Histor Osteoporosis y Term: Start Date: Feb/UNK/ 2020 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

1.n Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:21:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:21:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Osteoporosis	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:21:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Feb/UNK/2020	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:21:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

I.o

Date	Location	User	Value	Reason
Aug-25-2020 09:22:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 15 ber: Medical Histor Rosacea (y Term: mild) Start Date: Sep/12/20 11 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

1.o Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:22:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:22:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Rosacea (mild)	Initial Entry

1.o Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:22:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Sep/12/2011	Initial Entry

1.o Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:22:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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l.p

Date	Location	User	Value	Reason
Aug-27-2020 14:00:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Line/MH 16 Number: Medical History Term Complete Hysterectomy : Start Date: UNK/UNK/1989 Ongoing: NO End Date: UNK/UNK/1989	Transcription Error
Aug-25-2020 09:22:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: N 16 Medical History Term: Complete Hysterectomy Start Date: UNK/UNK/1989 Ongoing: YES	Initial Entry

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Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

1.p Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:22:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:22:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Complete Hysterectomy	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:22:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: UNK/UNK/1989	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
Sep-01-2020 18:05:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 1: Closed	Response satisfies query

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061098**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04

Aug-27-2020 14:00:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-27-2020 14:00:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO End Date: UNK/UNK/1989	Transcription Error
Aug-26-2020 19:09:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 1: Opened	ClinQuery: HYSTERECTOMY: As this is a procedure, please provide stop date.
Aug-25-2020 09:22:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

l.q

Date	Location	User	Value	Reason
Aug-27-2020 14:00:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Line/MH 17 Number: Medical Hi Post Partum story Term Hemorrhage : Start Date: UNK/UNK/1 989	Transcription Error

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
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Site Name: (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098
Subject Initials: ---
Generated By: pfe.levissc
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			Ongoing: NO End Date: UNK/UNK/1989	
Aug-25-2020 09:23:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 17 Medical History Term: Post Partum Hemorrhage Start Date: UNK/UNK/1989 Ongoing: YES	Initial Entry

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Header Text: c4591001

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1.q Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:23:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Aug-27-2020 14:05:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Closed	Response satisfies query
Aug-27-2020 14:01:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Changed data per query
Aug-26-2020 10:51:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Opened	GPDClin: Please confirm if this is a past condition (resolved after hysterectomy 1989). If yes, please add End Date.

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-25-2020 09:23:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Post Partum Hemorrhage	Initial Entry

1.q Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:23:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: UNK/UNK/1989	Initial Entry

1.q Ongoing:

Date	Location	User	Value	Reason
Aug-27-2020 14:00:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: NO End Date: UNK/UNK/1989	Transcription Error
Aug-25-2020 09:23:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

1.r

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-25-2020 09:23:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 18 ber: Medical Histor Postmenop y Term: ausal Start Date: UNK/UN K/1989 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

I.r Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:23:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:23:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Postmenopausal	Initial Entry

I.r Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:23:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: UNK/UNK/1989	Initial Entry

I.r Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:23:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

I.s

Date	Location	User	Value	Reason
Aug-25-2020 09:23:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 19 ber: Medical Histor Urethral SI y Term: ing Start Date: UNK/UN K/2018 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

I.s Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:23:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:23:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Urethral Sling	Initial Entry

I.s Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:23:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: UNK/UNK/2018	Initial Entry

I.s Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:23:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

I.t

Date	Location	User	Value	Reason
Aug-25-2020 09:24:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 20 mber: Medical Hist Bilateral Eye ory Term: Cataracts Start Date: Oct/20/2016 Ongoing: NO End Date: Feb/16/20 17	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:04

1.t Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:24:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:24:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Bilateral Eye Cataracts	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:24:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Oct/20/2016	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:24:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NO End Date: Feb/16/2017	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

I.u

Date	Location	User	Value	Reason
Aug-25-2020 09:25:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 21 Number: Medical History Term: Basal Cell Carcinoma (Forehead) Start Date: Sep/11/2011 : Ongoing: NO End Date: Sep/11/2011	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

1.u Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:25:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:25:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Basal Cell Carcinoma (Forehead)	Initial Entry

1.u Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:25:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Sep/11/2011	Initial Entry

1.u Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:25:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NO End Date: Sep/11/2011	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

I.v

Date	Location	User	Value	Reason
Aug-25-2020 09:26:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 22 Number: Medical History History of Recu History Term: rrent Actinic Ke ratosis Start Date Sep/6/2011 : Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.lewissc **Generated Time (GMT):** 29-Mar-2021 04:04

I.v Line/MH Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:26:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 09:26:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: History of Recurrent Actinic Keratosis	Initial Entry

I.v Start Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:26:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Sep/6/2011	Initial Entry

I.v Ongoing:

Date	Location	User	Value	Reason
Aug-25-2020 09:26:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

I.w

Date	Location	User	Value	Reason
Sep-16-2020 08:28:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 23 mber: Medical Hist Restless Leg ory Term: Syndrome Start Date: UNK/UNK/ 2000 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

I.w Line/MH Number:

Date	Location	User	Value	Reason
Sep-16-2020 08:28:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 08:28:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Restless Leg Syndrome	Initial Entry

I.w Start Date:

Date	Location	User	Value	Reason
Sep-16-2020 08:28:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: UNK/UNK/2000	Initial Entry

I.w Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 08:28:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

L.x

Date	Location	User	Value	Reason
Oct-23-2020 13:42:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 24 Number: Medical History Postural Orthostatic Tachycardia Term: Syndrome Start Date: UNK/UNK/1966 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject No:** 10061098**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:04***I.x Line/MH Number:***

Date	Location	User	Value	Reason
Oct-23-2020 13:42:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 24	Initial Entry

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

Date	Location	User	Value	Reason
Oct-23-2020 13:42:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Postural Orthostatic Tachycardia Syndrome	Initial Entry

I.x Start Date:

Date	Location	User	Value	Reason
Oct-23-2020 13:42:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: UNK/UNK/1966	Initial Entry

I.x Ongoing:

Date	Location	User	Value	Reason
Oct-23-2020 13:42:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES	Initial Entry

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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

I.y

Date	Location	User	Value	Reason
Oct-27-2020 16:24:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Line/MH Number: 25 Medical History Term: Ehlers-Danlos Syndrome Start Date: UNK/UNK/1966 Ongoing: YES	Changed Information
Oct-26-2020 17:32:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 25 Medical History Term: Ehlers-Danlos Start Date: UNK/UNK/1966 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

1.y Line/MH Number:

Date	Location	User	Value	Reason
Oct-26-2020 17:32:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 25	Initial Entry

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

Date	Location	User	Value	Reason
Oct-27-2020 22:20:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Oct-27-2020 16:24:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-27-2020 16:24:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Ehlers-Danlos Syndrome	Changed Information
Oct-27-2020 01:24:28 (UTC-07:00) Mountain	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify EHLERS-DANLOS as follows...The

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

Time (US & Canada)				term appears incomplete. If reporting EHLERS-DANLOS SYNDROME, update the verbatim term as such. Otherwise clarify and update the term as appropriate. Thank you.
Oct-26-2020 17:32:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry : Ehlers-Danlos	Initial Entry

1.y Start Date:

Date	Location	User	Value	Reason
Oct-26-2020 17:32:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: UNK/UNK/1966	Initial Entry

1.y Ongoing:

Date	Location	User	Value	Reason
Oct-26-2020 17:32:09	ACV0PFEINFP6000	Lindsey Bevan	Data Entry: YES	Initial Entry

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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

(UTC-07:00)
Mountain Time (US
& Canada)

(pfe.lbevan)

I.z

Date	Location	User	Value	Reason
Oct-26-2020 17:32:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 26 Number: Medical Hi Recurrent Urin story Term ary Tract Infect : ion Start Date: UNK/UNK/19 74 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

[Back to Form](#)

1.z Line/MH Number:

Date	Location	User	Value	Reason
Oct-26-2020 17:32:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 26	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 17:32:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Recurrent Urinary Tract Infection	Initial Entry

1.z Start Date:

Date	Location	User	Value	Reason
Oct-26-2020 17:32:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: UNK/UNK/1974	Initial Entry

1.z Ongoing:

Date	Location	User	Value	Reason
Oct-26-2020 17:32:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

1.aa

Date	Location	User	Value	Reason
Oct-26-2020 17:32:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 27 umber: Medical Hist Environment ory Term: al Allergies Start Date: UNK/UNK/1 969 Ongoing: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

1.aa Line/MH Number:

Date	Location	User	Value	Reason
Oct-26-2020 17:32:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 27	Initial Entry

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

Date	Location	User	Value	Reason
Oct-26-2020 17:32:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Environmental Allergies	Initial Entry

1.aa Start Date:

Date	Location	User	Value	Reason
Oct-26-2020 17:32:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: UNK/UNK/1969	Initial Entry

1.aa Ongoing:

Date	Location	User	Value	Reason
Oct-26-2020 17:32:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:26:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Aug/24/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-25-2020 09:26:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: 133.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 09:26:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-25-2020 09:26:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: 65.75	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:51 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

& Canada)				
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5. Unit:

Date	Location	User	Value	Reason
Aug-25-2020 09:26:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-25-2020 09:26:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21.7	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-25-2020 09:26:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Record Identif 1 ier:: Temperature: 98.3 Temperature F Unit: Temperature ORAL C Location:: AVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
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090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:51 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

Aug-25-2020 09:26:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: 1	Initial Entry
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7.a Temperature:

Date	Location	User	Value	Reason
Aug-25-2020 09:26:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: 98.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 09:26:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-25-2020 09:26:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-25-2020 09:27:15 (UTC-07:00)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

Mountain Time (US & Canada)				
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5. Specimen Type:

Date	Location	User	Value	Reason
Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Not Applicable	Initial Entry

6.a Test:

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-25-2020 09:27:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Not Applicable	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-25-2020 09:27:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Aug/24/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-25-2020 09:27:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: 236124	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

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
Aug-25-2020 09:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 09:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-26-2020 08:37:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-26-2020 01:03:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family
Clinic**Subject No:** 10061098**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

				appropriate.
Aug-25-2020 09:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 09:28:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-26-2020 08:37:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BHV2YP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:37:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BHV2YP	Initial Entry

5.b

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-26-2020 08:37:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BHV2YR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:37:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BHV2YR	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-26-2020 08:37:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BHV2YS	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:37:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BHV2YS	Initial Entry

5.d

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Aug-26-2020 08:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BJ7LYK	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:37:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BJ7LYK	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-26-2020 08:37:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BJ7LYL	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:37:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BJ7LYL	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

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
Aug-25-2020 09:28:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 09:28:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-26-2020 08:38:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-26-2020 01:07:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family
 Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

				appropriate.
Aug-25-2020 09:28:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 09:28:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-26-2020 08:38:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Sample ID: BHV2PZ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-26-2020 08:38:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: BHV2PZ	Initial Entry

090177e196ae3d2\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-25-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-25-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-25-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-25-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: Aug/24/2020 13:34	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

& Canada)				
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5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-25-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-25-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-25-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-25-2020 09:28:53 (UTC-07:00) Mountain Time (US	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFI ED OBSERVATION PERIO D	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (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, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

& Canada)				
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II. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-25-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: YES	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1006

Subject No: 10061098

Generated By: pfe.lewissc

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-25-2020 09:29:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECT ED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.lewissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-16-2020 08:19:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Sep/15/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1006

Subject No: 10061098

Generated By: pfe.lewissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-16-2020 08:19:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Sep/15/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-16-2020 08:19:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Record Identifier:: Temperature: 98.4 Temperature Unit: F Temperature Location:: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 08:19:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
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090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Sep-16-2020 08:19:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: 98.4	Initial Entry
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2.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 08:19:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-16-2020 08:19:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-16-2020 08:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-16-2020 08:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-16-2020 08:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Sep/15/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-16-2020 08:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: STUDY SITE	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-16-2020 08:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-16-2020 08:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-De 113 fined Identi fier: Test:: Choriogonado tropin Beta_P X113 Result:: Not Done:: NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-16-2020 08:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-16-2020 08:19:51 (UTC-07:00)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Choriogonadotropin Beta_ PX113	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

Mountain Time (US & Canada)				
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6.a Not Done:

Date	Location	User	Value	Reason
Sep-16-2020 08:19:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: NOT DONE	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

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
Sep-16-2020 08:19:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 08:19:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 08:20:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 08:19:59 (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.

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001
Visit: V2_VAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
 - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family
 Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

Sep-16-2020 08:19:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: YES Date of Collection: Sep/15/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Sep-16-2020 08:20:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Sample ID: BCT8JS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 08:20:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: BCT8JS	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-16-2020 08:20:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-16-2020 08:20:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-16-2020 08:20:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-16-2020 08:20:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Sep/15/2020 15:51	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 08:20:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-16-2020 08:20:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-16-2020 08:20:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-16-2020 08:20:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
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090177e196ae3d2\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Sep-16-2020 08:20:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<u>Data Entry:</u> YES	Initial Entry
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Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 14:18:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Oct/19/2020	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

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
Oct-19-2020 14:17:51 (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-19-2020 14:17:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-19-2020 14:18:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 14:17:51 (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.

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

Oct-19-2020 14:17:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: YES Date of Collection: Oct/19/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Oct-19-2020 14:18:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Sample ID: BCT8F3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 14:18:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: BCT8F3	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 14:18:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Sample ID: BJ7M8J	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 14:18:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: BJ7M8J	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 14:18:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Sample ID: BJ7MFK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 14:18:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: BJ7MFK	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-09-2021 17:10:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ashley Bragg (pfe.abragg)	<u>Data Entry:</u> Mar/9/2021	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1006

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

Subject No: 10061098

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
Mar-09-2021 17:10:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-09-2021 17:10:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-11-2021 10:54:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Mar-10-2021 04:40:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe.nairr29)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001**Visit:** V4_MONTH6_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Verified**Site No:** 1006**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family
Clinic**Subject No:** 10061098**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

				appropriate.
Mar-09-2021 17:10:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-09-2021 17:10:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ashley Bragg (pfe.abragg)	Data Entry: YES Date of Collection: Mar/9/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-11-2021 10:54:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kenadie Hamblin (pfe.khamblin)	Data Entry: Sample ID: BS8WTV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 10:54:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kenadie Hamblin (pfe.khamblin)	Data Entry: BS8WTV	Initial Entry

5.b

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

Date	Location	User	Value	Reason
Mar-11-2021 10:54:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kenadie Hamblin (pfe.khamblin)	Data Entry: Sample ID: BS8WP2	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 10:54:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kenadie Hamblin (pfe.khamblin)	Data Entry: BS8WP2	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-11-2021 11:08:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kenadie Hamblin (pfe.khamblin)	Data Entry: Sample ID: BRBMF5	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 11:08:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kenadie Hamblin (pfe.khamblin)	Data Entry: BRBMF5	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-19-2020 14:18:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 14:18:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 14:18:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Data Entry: COMPLETED	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - 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: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

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Date	Location	User	Value	Reason
Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

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
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

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
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061098

Generated By: pfe.lewissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-16-2020 08:21:15 (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
Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Headache	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: Aug/24/2020 14:30	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

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Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
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Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: NO End Date Time: Aug/25/2020 07:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
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Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
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Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: RECOVERED/RESOLVE D	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 08:21:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	Data Entry: NO	Initial Entry

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1. Category:

Date	Location	User	Value	Reason
Oct-19-2020 16:06:24 (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
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: ATRIAL FIBRILLATI ON INTERMITTENT	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-19-2020 16:06:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: Oct/6/2020 UNK:UN K	Transcription Error

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061098**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04

Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: Oct/12/2020 UNK:UN K	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-19-2020 16:06:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NO End Date Time: Oct/12/2020 UNK: UNK	Transcription Error
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NO	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

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

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Date	Location	User	Value	Reason
Oct-29-2020 15:03:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 3: Closed	Response satisfies query
Oct-29-2020 12:41:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Oct-29-2020 12:41:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<p>Data Entry: 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>NO</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p>	Transcription Error

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			Is this serious event life threatening? NO Other medically important serious event YES	
Oct-29-2020 12:18:36 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 3: Opened	Only the seriousness criteria "Other medically important serious event" is answered, all other serious criterias are left blank. Please answer all seriousness criteria questions with "Yes" or "No" response. Thank you.
Oct-20-2020 04:14:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 00:23:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 2: Closed	Response satisfies query
Oct-19-2020	ACV0PFEINFP6000	Madeline Kay	Query 2: Answered	Query is

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Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
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16:07:13 (UTC-07:00) Mountain Time (US & Canada)		Maldonado (pfe.mmaldonado)		ambiguous
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE ATRIAL FIBRILLATION INTERMITTENT: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: YES Other medically important serious event YES	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 16:06:24 (UTC-07:00)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NO	Initial Entry

Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
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Site No: 1006 **Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic
Subject No: 10061098 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 04:04

Mountain Time (US & Canada)				
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-22-2020 02:11:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	comment added.
Oct-21-2020 09:35:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Changed data per query
Oct-20-2020 11:24:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Please specify the concomitant drug that led to this AE. Please consider adding the name of the drug here or as a comment.
Oct-19-2020 16:08:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT	Transcription Error
Oct-19-2020	ACV0PFEINFP6000	Madeline Kay	Data Entry:	Initial Entry

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16:06:24 (UTC-07:00) Mountain Time (US & Canada)		Maldonado (pfe.mmaldonado)	NOT RELATED	
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020	ACV0PFEINFP6000	auto query	Query 1: Closed	Close Auto Query

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16:06:55 (UTC-07:00) Mountain Time (US & Canada)		(autoquery)		
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE ATRIAL FIBRILLATION INTERMITTENT: Response to "What was the outcome of this adverse event?" is 3 but End Date/Time is missing.
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: RECOVERED/RES OLVED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 16:06:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Oct-20-2020 04:14:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020405640	Initial Entry

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Subject Initials: ---

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1. Category:

Date	Location	User	Value	Reason
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: URINARY TRACT IN FECTION	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: Oct/3/2020 UNK:UNK	Initial Entry

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Header Text: c4591001

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Generated By: pfe.levisse

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Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NO End Date Time: Oct/12/2020 UNK:U NK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-19-2020 16:09:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: 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
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

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Date	Location	User	Value	Reason
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> BACTERIAL INFECTION	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-27-2020	ACV0PFEINFP6000	Kathryn Sewell	Query 1: Closed	Query closed;

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20:09:15 (UTC-07:00) Mountain Time (US & Canada)		(pfe.sewelk02)		will follow for SAE update on antibiotics, if med record received
Oct-21-2020 09:36:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Medical records have been requested
Oct-20-2020 11:14:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL SAE report states Bactrim given for UTI from Oct 3-6, then stopped (not working) and Cipro begun; however both have start dates of Oct 3. Please clarify if start date is incorrect, or narrative should state both begun Oct 3.
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
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Header Text: c4591001
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Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NO	Initial Entry
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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: RECOVERED/RESOL VED	Initial Entry

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

Date	Location	User	Value	Reason
Oct-19-2020 16:09:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: NO	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

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: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

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Date	Location	User	Value	Reason
Oct-19-2020 16:10:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levisse

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

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-19-2020 16:10:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-19-2020 16:10:09 (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-19-2020 16:10:09 (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-19-2020 16:10:09 (UTC-07:00)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: INFLUENZA VACCIN E	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

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, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.levissc

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

Mountain Time (US & Canada)				
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5. Date:

Date	Location	User	Value	Reason
Oct-19-2020 16:10:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madeline Kay Maldonado (pfe.mmaldonado)	Data Entry: Oct/2/2020	Initial Entry

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: 10061098

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
Feb-26-2021 08:18:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Bradley Young (pfe.byoung)	Data Entry: Jan/18/2021	Transcription Error
Jan-25-2021 13:38:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Jan/25/2021	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1006

Subject No: 10061098

Generated By: pfe.lewissc

Form: FURTHER VACCINATION CONFIRMATION - 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 - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-25-2021 13:38:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001
Visit: Disposition - Unscheduled **Form:** TREATMENT UNBLINDED - 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: 10061098 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:04

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-25-2021 13:38:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: Jan/25/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-25-2021 13:38:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Data Entry: ASSESS ELIGIBILITY F OR ADDITIONAL VACCI NATION	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1006

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

Subject No: 10061098

Subject Initials: ---

Generated By: pfe.lewissc

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-19-2020 14:18:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Aug-25-2020 09:27:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZE D	Initial Entry
Aug-25-2020 09:06:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-19-2020 14:18:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/19/2020	Initial Entry
Aug-25-2020 09:27:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/24/2020	Initial Entry
Aug-25-2020 09:06:17	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/24/2020	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061098

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

(UTC-07:00) Mountain Time (US & Canada)				
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090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)

Header Text: c4591001

Visit: Investigator Signature -
Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061098

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - 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. Casebook Signature

Date	Location	User	Value	Reason
Oct-30-2020 14:08:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	James Peterson (pfe.jpeterson)	Data Entry: Click Here to Enable	Initial Entry

090177e196ae3d22\Final\Final On: 01-Apr-2021 04:27 (GMT)