

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.lewissc

**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 Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/12/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** DEMOGRAPHY

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10061020]
2.	Birth Date:	(b) (6) /1944
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**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/12/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable _____
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Aug/12/2020
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: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DIABETES TYPE 2]
	Start Date:	Aug/21/1995
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CAUTERIZED ULCERS ON DUODENUM]
	Start Date:	Feb/9/2008
	Ongoing:	NO End Date: Feb/9/2020
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BOWEL BLOCKAGE]
	Start Date:	Apr/1/2008
	Ongoing:	NO End Date: Apr/1/2008
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BOWEL BLOCKAGE REMOVAL]
	Start Date:	Apr/1/2008
	Ongoing:	NO End Date: Apr/1/2008

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**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.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CATARACT SURGERY]
	Start Date:	Aug/UNK/2010
	Ongoing:	NO End Date: Aug/UNK/2010
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HEART ATTACK]
	Start Date:	Dec/UNK/1989
	Ongoing:	NO End Date: Dec/UNK/1989
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HEART ATTACK]
	Start Date:	Mar/25/2004
	Ongoing:	NO End Date: Mar/UNK/2004
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CARDIAC STENT PLACEMENT]
	Start Date:	Mar/25/2004
	Ongoing:	NO End Date: Mar/25/2004

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**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.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HEART ATTACK]
	Start Date:	Mar/UNK/2017
	Ongoing:	NO End Date: Mar/UNK/2017
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CARDIAC STENT PLACEMENT]
	Start Date:	Mar/UNK/2017
	Ongoing:	NO End Date: Mar/UNK/2017
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CORONARY ARTERY DISEASE]
	Start Date:	UNK/UNK/1989
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[PLANTAR FACIITIS OF RIGHT FOOT]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[FLATULENCE]
	Start Date:	UNK/UNK/2008
	Ongoing:	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**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 n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[POLYNEUROPATHY, DIABETIC BILATERAL FEET]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[XEROSIS CUTIS]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERCHOLESTEROLEMIA]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERTENSION]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1 r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ANAL FISSURE]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

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.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[FACTOR 5 LIDEN]
	Start Date:	(b) (6) /1944
	Ongoing:	YES
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DEEP VEIN THROMBOPHLEBITIS RIGHT LEG]
	Start Date:	UNK/UNK/1983
	Ongoing:	YES
1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[LEFT BACK PAIN]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.v	Line/MH Number:	[22]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RECURRENT BILATERAL LOWER EXTREMITIES EDEMA]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.w	Line/MH Number:	[23]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BASAL CELL CARCINOMA, RECURRENT, MULTIPLE LOCATIONS]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**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.x	Line/MH Number:	[24]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CORONARY ATHEROSCLEROSIS]
	Start Date:	Dec/UNK/1989
	Ongoing:	YES
1.y	Line/MH Number:	[25]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MITRAL VALVE PROLAPSE]
	Start Date:	UNK/UNK/1989
	Ongoing:	NO End Date: Aug/27/2020
1.z	Line/MH Number:	[26]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RECURRENT PEPTIC ULCER]
	Start Date:	UNK/UNK/1980
	Ongoing:	YES
1.aa	Line/MH Number:	[27]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[TRANSIENT ISCHEMIC ATTACK]
	Start Date:	Jan/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.ab	Line/MH Number:	[28]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[TRANSIENT ISCHEMIC ATTACK]
	Start Date:	Jul/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**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.ac	Line/MH Number:	[29]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[CARDIOVASCULAR ACCIDENT]
	Start Date:	Mar/6/2019
	Ongoing:	NO End Date: Mar/UNK/2019
1.ad	Line/MH Number:	[30]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[RIGHT BUNDLE BRANCH BLOCK]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/12/2020
2.	Weight:	[177.0]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[24.0]

**Vital Signs Details**

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

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**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/12/2020
2.	Randomization Number:	[226866]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/12/2020
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	[BLX0FL]
5.b	Sample ID	[BLX0FM]
5.c	Sample ID	[BLX0FN]
5.d	Sample ID	[BLZ8B7]
5.e	Sample ID	[BLZ8B8]

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/12/2020
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	[BHV2MM]
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090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/12/2020 11:32
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

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1006

**Subject No:** 10061020

**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	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levisse

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Not Done _____ //	<a href="#">Comments</a>
2.	Erroneous Visit	Not Done _____	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Not Started

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	
2.	Symptom:	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	
3.	Injection Site Location:	
4.	Injection Site Body Side:	
5.	Injection Site Reaction:	
	Were injection site reactions present on the last day the Subject Diary was completed?	

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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 20-Feb-2021 02:16

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** VITAL SIGNS - TEMP

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Vital Signs**

1.	Date:	//
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**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** VACCINATION

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**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?	

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**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**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:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Not Started

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	
2.	Symptom:	
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	
3.	Injection Site Location:	
4.	Injection Site Body Side:	
5.	Injection Site Reaction:	
	Were injection site reactions present on the last day the Subject Diary was completed?	

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_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:** 10061020

**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	[ ]
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090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**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:** V4\_MONTH6\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**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 Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**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:** 10061020

**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\_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:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:	[ ]
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**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:** 10061020

**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	[ ]
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**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:** 10061020

**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	[ ]
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**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:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:	[ ]
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	
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**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:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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:	

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**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:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

**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:** 10061020

**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	[ ]
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**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1006

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

**Subject No:** 10061020

**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:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Unplanned Assessments**

1.	Assessments	
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**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:** 10061020

**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 :	Sep/16/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levisse

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	Sep/16/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	ADVERSE EVENT
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:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.lewissc

**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:	
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**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:** 10061020

**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	[ ]
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090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (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: 10061020

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	CORONARY ARTERY OCCLUSION	Aug/25/2020 UNK:UNK	NO End Date Time:  Aug/27/2020 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	DYSPNEA ON EXERTION	Aug/25/2020 UNK:UNK	NO End Date Time:  Aug/27/2020 UNK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	ANGINA	Aug/21/2020 UNK:UNK	NO End Date Time:  Aug/27/2020 UNK:UNK	<a href="#">Repeating Pages</a>
4.	ADVERSE EVENT	4	NON-ST ELEVATED MYOCARDIAL INFARCTION	Aug/25/2020 UNK:UNK	NO End Date Time:  Aug/27/2020 UNK:UNK	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	MITRAL VALVE REGURGITATION	Aug/25/2020 UNK:UNK	NO End Date Time:  Aug/27/2020 UNK:UNK	<a href="#">Repeating Pages</a>

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061020

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

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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)	[CORONARY ARTERY OCCLUSION]
4.	Start Date Time:	Aug/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/27/2020 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? YES  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [CORONARY ATHEROSCLEROSIS]

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**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

10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020336034]

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**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:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[DYSPNEA ON EXERTION]
4.	Start Date Time:	Aug/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/27/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [CORONARY ATHEROSCLEROSIS]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen

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

**Subject Initials:** ---

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

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	[ ]

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**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)	[ANGINA]
4.	Start Date Time:	Aug/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/27/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [CORONARY ATHEROSCLEROSIS]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen

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

**Subject Initials:** ---

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

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	[ ]

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**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:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[NON-ST ELEVATED MYOCARDIAL INFARCTION]
4.	Start Date Time:	Aug/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/27/2020 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
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: [CORONARY ARTEROSCLEROSIS]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen

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

**Subject Initials:** ---

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

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	[ ]



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[MITRAL VALVE REGURGITATION]
4.	Start Date Time:	Aug/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/27/2020 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
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: [PROGRESSION OF MYXOMATOUS MITRAL VALVE]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen

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

**Subject Initials:** ---

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

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	[ ]

**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:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Category	Medication Error	Start Date	Is the medication error Still On going	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** MEDICATION ERROR

**Form Status:** Not Started

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

**Subject Initials:** ---

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

[Back to Form](#)

**Medication Error**

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

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**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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**Concomitant Medications**

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

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

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

**Subject No:** 10061020

**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.						<a href="#">Repeating Pages</a>

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**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

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**Concomitant Medications**

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

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)



**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

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

**Subject Initials:** ---

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

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**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

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**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:** 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:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Vital Signs**

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

**Vital Signs Details**

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

**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:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Vaccination**

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

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Informed Consent - Asymptomatic Surveillance**

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

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1006

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

**Subject No:** 10061020

**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	[ ]
----	-----------	-----

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Not Started

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

**Further Vaccination Confirmation**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levisse

**Form:** TREATMENT UNBLINDED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Treatment Unblinded**

1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	Sep/16/2020
----	------------------------------	-------------

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

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

**Subject Initials:** ---

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

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levisse

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Sep/16/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levisse

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, 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](#)

**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, Signed, Verified

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levisse

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

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
James Peterson	Approved	Nov-13-2020 17:23:03 (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.

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** INCLUSION/EXCLUSION CRITERIA - Comments

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Sep-17-2020 12:15:54 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Applicable
Form	Sep-16-2020 11:29:00 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	due to subject change in health they no longer meet criterion as of 16Sep2020 and have been discontinued from the trial
Form	Sep-16-2020 11:02:06 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	
Form	Aug-12-2020 18:11:50 (UTC-07:00) Mountain Time (US & Canada)	Emily Wilcox (pfe.ewilcox)	Not Applicable

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - Comments

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
Form	Nov-06-2020 12:20:42 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - Comments

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
1	Nov-06-2020 12:20:42 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - Comments

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

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Item	Date	User	Comment
2	Nov-06-2020 12:20:42 (UTC-07:00) Mountain Time (US & Canada)	Lindsey Bevan (pfe.lbevan)	Not Done

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
James Peterson	Approved	Nov-13-2020 17:23:03 (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.

Colby Bostock	N/A	Nov-12-2020 14:34:27 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

James Peterson	Approved	Nov-09-2020 13:09:24 (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.

Lindsey Bevan	N/A	Nov-06-2020 12:20:42 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

James Peterson	Approved	Oct-13-2020 11:59:30 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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	Oct-13-2020 09:45:14 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

James Peterson	Approved	Sep-22-2020 17:54:42 (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.

Lindsey Bevan	N/A	Sep-22-2020 11:53:11 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

James Peterson	Approved	Sep-21-2020 17:16:15 (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.

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090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.lewissc

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

Lindsey Bevan	N/A	Sep-21-2020 10:58:01 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**  
N/A

James Peterson	Approved	Sep-18-2020 18:40:30 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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**Affidavit:**  
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To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Lindsey Bevan	N/A	Sep-18-2020 14:56:24 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**  
N/A

James Peterson	Approved	Sep-17-2020 12:21:11 (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.

Lindsey Bevan	N/A	Sep-17-2020 12:13:51 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**  
N/A

James Peterson	Approved	Sep-16-2020 21:47:42 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
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090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

**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	Sep-16-2020 10:48:24 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

James Peterson	Approved	Sep-10-2020 21:45:14 (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.

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**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-12-2020 18:10:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 18:10:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-12-2020 18:11:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/12/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-12-2020 18:10:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10061020	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-12-2020 18:10:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1944	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-12-2020 18:11:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-12-2020 18:11:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 18:11:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-06-2020 13:38:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Laurie Hawes (pfe.hawesl01)	Query 1: Closed	Response satisfies query
Nov-06-2020 12:20:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Changed data per query
Nov-06-2020 01:09:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Opened	At the time disposition treatment CRF was completed, visit 2 was due based on protocol defined window period. In case visit 2 was not performed, please complete visit 2 date of CRF with form level comment as NOT DONE and leave all other CRFs blank.
Aug-12-2020 18:11:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> Aug/12/2020	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:29

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Sep-17-2020 12:15:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> <b>Criterion Description:</b>	Changed Information
Sep-16-2020 11:02:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> <b>Crite</b> Participants who are willing a <b>ri</b> on nd able to comply with all sch <b>Desc</b> eduled visits, vaccination pla <b>ripti</b> n, laboratory tests, lifestyle co <b>on:</b> nsiderations, and other study procedures	Initial Entry

*I.a Description of Inclusion Criterion Not Met*

Date	Location	User	Value	Reason
Sep-18-2020 04:18:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Closed	Not Applicable added
Sep-17-2020 12:15:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-17-2020 12:15:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b>	Changed Information
Sep-17-2020 00:29:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Avinash Gawas (pfe.gawasa)	Query 1: Opened	PDQ: Inclusion criteria have been added, vaccination details present. Inclusion/Exclusion is expected only for Screen Failure and subjects randomized in error. Please add Form level comment "Not Applicable" if Incl/Excl was added in error or confirm.
Sep-16-2020 11:02:20 (UTC-07:00) Mountain	ACV0PFEINFP6000	Lindsey Bevan	<b>Data Entry:</b> Participants who are willing and abl	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

Time (US & Canada)		(pfe.lbevan)	e to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures	
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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-12-2020 18:11:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> Aug/12/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-12-2020 18:11:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-12-2020 18:11:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Aug-13-2020 09:27:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number 1</b> : <b>Medical History Term:</b> DIABETES TYPE 2 <b>Start Date:</b> Aug/21/1995 <b>Ongoing:</b> YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 09:27:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:27:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> DIABETES TYPE 2	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 09:27:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Aug/21/1995	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 09:27:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

I.b

Date	Location	User	Value	Reason
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090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

Aug-18-2020 14:02:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	<b>Data Entry:</b> <b>Line/MH N 2</b> <b>umber:</b> <b>Medical Hi</b> CAUTERIZED ULCE <b>story Term:</b> RS ON DUODENUM <b>Start Date:</b> Feb/9/2008 <b>Ongoing:</b> NO End Date: Feb/9/2020	Stop date provided.
Aug-13-2020 09:28:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 2</b> <b>umber:</b> <b>Medical His</b> CAUTERIZED ULCE <b>tory Term:</b> RS ON DUODENUM <b>Start Date:</b> Feb/9/2008 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 09:28:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:28:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> CAUTERIZED ULCERS ON DUO DENUM	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 09:28:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Feb/9/2008	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Aug-19-2020 18:42:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Closed	Response satisfies query
Aug-18-2020 14:02:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Stop date provided.
Aug-18-2020 14:02:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	<b>Data Entry:</b> NO End Date:  Feb/9/2020	Stop date provided.
Aug-15-2020 22:17:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Opened	CAUTERIZED ULCERS ON DUODENUM : As this is a procedure, please can you provide a stop date
Aug-13-2020 09:28:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

I.c

Date	Location	User	Value	Reason
Aug-13-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 3 <b>r:</b> Medical History: BOWEL BLOCK Term: AGE Start Date: Apr/1/2008 Ongoing: NO End Date: Apr/1/2008	Initial Entry

I.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-13-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> BOWEL BLOCKAGE	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Apr/1/2008	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Aug-13-2020 09:28:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date: Apr/1/2008	Initial Entry

I.d

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061020

Subject Initials: ---

Generated By: pfe.levissc

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

Date	Location	User	Value	Reason
Aug-13-2020 09:29:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Nu 4 mber: Medical Hist BOWEL BLOCKAG ory Term: E REMOVAL Start Date: Apr/1/2008 Ongoing: NO End Date: Apr/1/2008	Initial Entry

*I.d Line/MH Number:*

Date	Location	User	Value	Reason
Aug-13-2020 09:29:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:29:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> BOWEL BLOCKAGE REMOVAL	Initial Entry

*I.d Start Date:*

Date	Location	User	Value	Reason
Aug-13-2020 09:29:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Apr/1/2008	Initial Entry

*I.d Ongoing:*

Date	Location	User	Value	Reason
Aug-13-2020 09:29:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date: Apr/1/2008	Initial Entry

*I.e*

Date	Location	User	Value	Reason
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090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Aug-13-2020 09:29:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Numb</b> 5 <b>er:</b> <b>Medical History</b> CATARACT SUR <b>Term:</b> GERY <b>Start Date:</b> Aug/UNK/2010 <b>Ongoing:</b> NO End Date:  Aug/UNK/2010	Initial Entry
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*I.e Line/MH Number:*

Date	Location	User	Value	Reason
Aug-13-2020 09:29:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:29:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> CATARACT SURGERY	Initial Entry

*I.e Start Date:*

Date	Location	User	Value	Reason
Aug-13-2020 09:29:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Aug/UNK/2010	Initial Entry

*I.e Ongoing:*

Date	Location	User	Value	Reason
Aug-13-2020 09:29:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date:  Aug/UNK/2010	Initial Entry

*I.f*

Date	Location	User	Value	Reason
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090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

Aug-13-2020 09:30:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> <b>Line/MH Number</b> 6 : <b>Medical History T HEART ATTA</b> <b>erm:</b> CK <b>Start Date:</b> Dec/UNK/1989 <b>Ongoing:</b> NO End Date:  Dec/UNK/1 989	Transcription Error
Aug-13-2020 09:30:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number</b> 6 : <b>Medical History T HEART ATTA</b> <b>erm:</b> CH <b>Start Date:</b> Dec/UNK/1989 <b>Ongoing:</b> NO End Date:  Dec/UNK/1 989	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

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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: 10061020

Subject Initials: ---

Generated By: pfe.levissc

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

**I.f Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 09:30:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:30:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> HEART ATTACK	Transcription Error
Aug-13-2020 09:30:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> HEART ATTACH	Initial Entry

**I.f Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 09:30:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Dec/UNK/1989	Initial Entry

**I.f Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 09:30:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date:  Dec/UNK/1989	Initial Entry

**I.g**

Date	Location	User	Value	Reason
Aug-13-2020 09:30:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Te</b> HEART ATTA <b>rm:</b> CK <b>Start Date:</b> Mar/25/2004	Initial Entry

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Form Version: 22-Apr-2020 21:03

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

Subject Initials: ---

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

			<b>Ongoing:</b>	NO End Date:  Mar/UNK/20 04
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**I.g Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 09:30:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:30:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> HEART ATTACK	Initial Entry

**I.g Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 09:30:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Mar/25/2004	Initial Entry

**I.g Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 09:30:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date:  Mar/UNK/2004	Initial Entry

**I.h**

Date	Location	User	Value	Reason
Aug-13-2020 09:31:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Nu 8 mber: <b>Medical Hist</b> CARDIAC STENT P <b>ory Term:</b> LACEMENT <b>Start Date:</b> Mar/25/2004	Initial Entry

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Site No: 1006

Subject No: 10061020

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

Subject Initials: ---

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

			<b>Ongoing:</b> NO End Date: Mar/25/2004	
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***I.h Line/MH Number:***

Date	Location	User	Value	Reason
Aug-13-2020 09:31:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:31:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> CARDIAC STENT PLACEMENT	Initial Entry

***I.h Start Date:***

Date	Location	User	Value	Reason
Aug-13-2020 09:31:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Mar/25/2004	Initial Entry

***I.h Ongoing:***

Date	Location	User	Value	Reason
Aug-13-2020 09:31:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date: Mar/25/2004	Initial Entry

***I.i***

Date	Location	User	Value	Reason
Aug-13-2020 09:32:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 9 <b>Medical History Te</b> HEART ATTA <b>rm:</b> CK <b>Start Date:</b> Mar/UNK/2017	Initial Entry

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**Header Text:** c4591001

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**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**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

			<b>Ongoing:</b> NO	
			End Date:	
			Mar/UNK/20	
			17	

***Li Line/MH Number:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-13-2020 09:32:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

***Li Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-13-2020 09:32:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> HEART ATTACK	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

[Back to Form](#)

*I.i Start Date:*

Date	Location	User	Value	Reason
Aug-13-2020 09:32:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Mar/UNK/2017	Initial Entry

*I.i Ongoing:*

Date	Location	User	Value	Reason
Aug-13-2020 09:32:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date:  Mar/UNK/2017	Initial Entry

*I.j*

Date	Location	User	Value	Reason
Aug-13-2020 09:32:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 10 <b>mber:</b> <b>Medical Hist</b> CARDIAC STENT P <b>ory Term:</b> LACEMENT <b>Start Date:</b> Mar/UNK/2017 <b>Ongoing:</b> NO End Date:  Mar/UNK/2017	Initial Entry

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Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

**I.j Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 09:32:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:32:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> CARDIAC STENT PLACEMENT	Initial Entry

**I.j Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 09:32:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Mar/UNK/2017	Initial Entry

**I.j Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 09:32:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date:  Mar/UNK/2017	Initial Entry

**I.k**

Date	Location	User	Value	Reason
Aug-13-2020 09:32:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Nu 11 mber: Medical Histo CORONARY ARTE ry Term: RY DISEASE Start Date: UNK/UNK/1989 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

**I.k Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 09:32:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

**I.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-13-2020 09:32:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> CORONARY ARTERY DISEASE	Initial Entry

**I.k Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 09:32:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/1989	Initial Entry

**I.k Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 09:32:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

**I.l**

Date	Location	User	Value	Reason
Aug-13-2020 09:33:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Nu 12 mber: Medical Hist PLANTAR FACIITIS ory Term: OF RIGHT FOOT Start Date: UNK/UNK/2016 Ongoing: YES	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

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Site No: 1006

Subject No: 10061020

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 09:33:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:33:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> PLANTAR FACIITIS OF RIGHT F OOT	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 09:33:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 09:33:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

**1.m**

Date	Location	User	Value	Reason
Aug-13-2020 09:33:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 13 Medical History Term: FLATULENC m: E Start Date: UNK/UNK/20 08 Ongoing: YES	Initial Entry

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Header Text: c4591001

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

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**I.m Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 09:33:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:33:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> FLATULENCE	Initial Entry

**I.m Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 09:33:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/2008	Initial Entry

**I.m Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 09:33:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

**I.n**

Date	Location	User	Value	Reason
Aug-13-2020 09:34:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> <b>Line/MH Number:</b> 14 <b>Medical History Term:</b> POLYNEUROPATHY, DIABETIC BILATERAL FEET <b>Start Date:</b> UNK/UNK/2016 <b>Ongoing:</b> YES	Transcription Error
Aug-13-2020 09:33:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 14	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

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

Subject Initials: ---

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

			<b>Medical History Term:</b> POLYNEUROPATHY, DIABETIC BILATERAL FEET <b>Start Date:</b> UNK/UNK/2016 <b>Ongoing:</b> YES	
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***Ln Line/MH Number:***

Date	Location	User	Value	Reason
Aug-13-2020 09:33:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 14	Initial Entry

***Ln Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-13-2020 09:34:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> POLYNEUROPATHY, DIABETIC BILATERAL FEET	Transcription Error
Aug-13-2020 09:33:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> POLYNEUROPATHY, DIABETIC BILATERAL FEET	Initial Entry

***Ln Start Date:***

Date	Location	User	Value	Reason
Aug-13-2020 09:33:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

***Ln Ongoing:***

Date	Location	User	Value	Reason
Aug-13-2020 09:33:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

***Lo***

Date	Location	User	Value	Reason
Aug-13-2020 09:36:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 15	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			<b>Medical History Term:</b> XEROSIS CUTIS <b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> YES	
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*I.o Line/MH Number:*

Date	Location	User	Value	Reason
Aug-13-2020 09:36:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 15	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:36:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> XEROSIS CUTIS	Initial Entry

*I.o Start Date:*

Date	Location	User	Value	Reason
Aug-13-2020 09:36:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

*I.o Ongoing:*

Date	Location	User	Value	Reason
Aug-13-2020 09:36:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

*I.p*

Date	Location	User	Value	Reason
Aug-13-2020 09:36:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 16 <b>Medical History Term:</b> HYPERCHOLESTEROLEMIA <b>Start Date:</b> UNK/UNK/2000 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

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

Subject Initials: ---

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

***I.p Line/MH Number:***

Date	Location	User	Value	Reason
Aug-13-2020 09:36:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 16	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:36:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> HYPERCHOLESTEROLEMIA	Initial Entry

***I.p Start Date:***

Date	Location	User	Value	Reason
Aug-13-2020 09:36:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/2000	Initial Entry

***I.p Ongoing:***

Date	Location	User	Value	Reason
Aug-13-2020 09:36:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

***I.q***

Date	Location	User	Value	Reason
Aug-13-2020 09:36:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 17 Medical History Term: HYPERTENSION Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

**I.q Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 09:36:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 17	Initial Entry

**I.q Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-13-2020 09:36:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> HYPERTENSION	Initial Entry

**I.q Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 09:36:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**I.q Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 09:36:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

**I.r**

Date	Location	User	Value	Reason
Aug-13-2020 09:36:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 18 Medical History Term: ANAL FISSURE Start Date: UNK/UNK/2018 Ongoing: YES	Initial Entry

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Header Text: c4591001

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Site No: 1006

Subject No: 10061020

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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

***L.r Line/MH Number:***

Date	Location	User	Value	Reason
Aug-13-2020 09:36:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 18	Initial Entry

***L.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-13-2020 09:36:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> ANAL FISSURE	Initial Entry

***L.r Start Date:***

Date	Location	User	Value	Reason
Aug-13-2020 09:36:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***L.r Ongoing:***

Date	Location	User	Value	Reason
Aug-13-2020 09:36:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

***L.s***

Date	Location	User	Value	Reason
Aug-13-2020 09:37:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 19 Medical History Te FACTOR 5 LID rm: EN Start Date: (b) (6) /1944 Ongoing: YES	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

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**I.s Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 09:37:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 19	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 18:42:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Closed	Response satisfies query
Aug-18-2020 13:40:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	Query 1: Answered	Not exclusionary per investigator.
Aug-17-2020 02:51:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Opened	There is a Med Hx entry of Factor V Leiden, please confirm if pt meets exclusions criteria #10.
Aug-13-2020 09:37:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> FACTOR 5 LIDEN	Initial Entry

**I.s Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 09:37:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> (b) (6)/1944	Initial Entry

**I.s Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 09:37:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

**I.t**

Date	Location	User	Value	Reason
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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Subject Initials: ---

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

Aug-13-2020 09:37:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 20 <b>Number:</b> <b>Medical Hi</b> DEEP VEIN THROMB <b>story Term</b> OPHLEBITIS RIGHT <b>:</b> LEG <b>Start Date:</b> UNK/UNK/1983 <b>Ongoing:</b> YES	Initial Entry
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***L.t Line/MH Number:***

Date	Location	User	Value	Reason
Aug-13-2020 09:37:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 20	Initial Entry

***L.t Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Aug-13-2020 09:37:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> DEEP VEIN THROMBOPHLEBITI S RIGHT LEG	Initial Entry

***L.t Start Date:***

Date	Location	User	Value	Reason
Aug-13-2020 09:37:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/1983	Initial Entry

***L.t Ongoing:***

Date	Location	User	Value	Reason
Aug-13-2020 09:37:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

***L.u***

Date	Location	User	Value	Reason
Aug-13-2020 09:37:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 21 <b>Medical History T</b> LEFT BACK P <b>erm:</b> AIN	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			<b>Start Date:</b>	UNK/UNK/1990
			<b>Ongoing:</b>	YES

**I.u Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 09:37:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:37:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> LEFT BACK PAIN	Initial Entry

**I.u Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 09:37:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

**I.u Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 09:37:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

**I.v**

Date	Location	User	Value	Reason
Aug-13-2020 09:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH 22 Number: Medical History T erm: RECURRENT BILATERAL LOWER EXTREMIT IES EDEMA Start Date: UNK/UNK/2000 e: Ongoing: YES	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

Subject Initials: ---

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

*I.v Line/MH Number:*

Date	Location	User	Value	Reason
Aug-13-2020 09:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 22	Initial Entry

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

Date	Location	User	Value	Reason
Aug-13-2020 09:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> RECURRENT BILATERAL LOWE R EXTREMITIES EDEMA	Initial Entry

*I.v Start Date:*

Date	Location	User	Value	Reason
Aug-13-2020 09:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/2000	Initial Entry

*I.v Ongoing:*

Date	Location	User	Value	Reason
Aug-13-2020 09:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

*I.w*

Date	Location	User	Value	Reason
Aug-18-2020 14:00:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	<b>Data Entry:</b> <b>Line/M</b> 23 <b>H Num</b> <b>er:</b> <b>Medical</b> BASAL CELL CARCIN <b>History</b> OMA, RECURRENT, M <b>Term:</b> MULTIPLE LOCATIONS <b>Start Da</b> UNK/UNK/2010 <b>te:</b> <b>Ongoing</b> YES :	Updated info.
Aug-13-2020 09:38:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> N 23	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

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**Site No:** 1006

**Subject No:** 10061020

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**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Subject Initials:** ---

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

			<b>umber:</b> <b>Medical His</b> BASAL CELL CARCI <b>tory Term:</b> NOMA, RECURREN T <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

**I.w Line/MH Number:**

Date	Location	User	Value	Reason
Aug-13-2020 09:38:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 23	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 18:42:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Closed	Response satisfies query
Aug-18-2020 14:00:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Updated info.
Aug-18-2020 14:00:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ty Henry (pfe.thenry)	<b>Data Entry:</b> BASAL CELL CARCINOMA, RECURRENT, MULTIPLE LOCATIONS	Updated info.
Aug-15-2020 22:08:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lingyan Zuo (pfe.zuol02)	Query 1: Opened	Please could you also provide the location (Eg; neck, Arm, Leg) of the Basal Cell Carcinoma
Aug-13-2020 09:38:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> BASAL CELL CARCINOMA, RECURRENT	Initial Entry

**I.w Start Date:**

Date	Location	User	Value	Reason
Aug-13-2020 09:38:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**I.w Ongoing:**

Date	Location	User	Value	Reason
Aug-13-2020 09:38:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

**I.x**

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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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
Sep-16-2020 15:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Nu 24 mber: Medical History Term: CORONARY ATHE ROSCLE Start Date: Dec/UNK/1989 Ongoing: YES	Initial Entry

*I.x Line/MH Number:*

Date	Location	User	Value	Reason
Sep-16-2020 15:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 24	Initial Entry

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

Date	Location	User	Value	Reason
Sep-16-2020 15:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> CORONARY ATHEROSCLEROSIS	Initial Entry

*I.x Start Date:*

Date	Location	User	Value	Reason
Sep-16-2020 15:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Dec/UNK/1989	Initial Entry

*I.x Ongoing:*

Date	Location	User	Value	Reason
Sep-16-2020 15:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

*I.y*

Date	Location	User	Value	Reason
Sep-16-2020 15:12:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Num 25 ber:	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)



Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.lewissc

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

Subject Initials: ---

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

			<b>Medical History Term:</b> MITRAL VALVE P ROLAPSE <b>Start Date:</b> UNK/UNK/1989 <b>Ongoing:</b> NO End Date: Aug/27/2020	
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**I.y Line/MH Number:**

Date	Location	User	Value	Reason
Sep-16-2020 15:12:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 25	Initial Entry

**I.y Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-16-2020 15:12:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> MITRAL VALVE PROLAPSE	Initial Entry

**I.y Start Date:**

Date	Location	User	Value	Reason
Sep-16-2020 15:12:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/1989	Initial Entry

**I.y Ongoing:**

Date	Location	User	Value	Reason
Sep-16-2020 15:12:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date: Aug/27/2020	Initial Entry

**I.z**

Date	Location	User	Value	Reason
Sep-16-2020 15:13:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Num 26 ber:	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			<b>Medical History Term:</b> RECURRENT PEP TIC ULCER <b>Start Date:</b> UNK/UNK/1980 <b>Ongoing:</b> YES	
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*I.z Line/MH Number:*

Date	Location	User	Value	Reason
Sep-16-2020 15:13:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 26	Initial Entry

*I.z Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Sep-16-2020 15:13:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> RECURRENT PEPTIC ULCER	Initial Entry

*I.z Start Date:*

Date	Location	User	Value	Reason
Sep-16-2020 15:13:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/1980	Initial Entry

*I.z Ongoing:*

Date	Location	User	Value	Reason
Sep-16-2020 15:13:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

*I.aa*

Date	Location	User	Value	Reason
Sep-16-2020 15:14:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 27 <b>Medical History Term:</b> TRANSIENT ISCHEMIC ATTACK <b>Start Date:</b> Jan/UNK/2016	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**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

			<b>Ongoing:</b> NO End Date:  UNK/UNK/2016	
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***1.aa Line/MH Number:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-16-2020 15:14:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 27	Initial Entry

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

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-16-2020 15:14:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> TRANSIENT ISCHEMIC ATTACK	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

*1.aa Start Date:*

Date	Location	User	Value	Reason
Sep-16-2020 15:14:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Jan/UNK/2016	Initial Entry

*1.aa Ongoing:*

Date	Location	User	Value	Reason
Sep-16-2020 15:14:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2016	Initial Entry

*1.ab*

Date	Location	User	Value	Reason
Sep-16-2020 15:14:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 28 <b>mber:</b> <b>Medical Hist</b> TRANSIENT ISCHE <b>ory Term:</b> MIC ATTACK <b>Start Date:</b> Jul/UNK/2018 <b>Ongoing:</b> NO End Date:  UNK/UNK/2018	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

**I.ab Line/MH Number:**

Date	Location	User	Value	Reason
Sep-16-2020 15:14:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry

**I.ab Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-16-2020 15:14:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> TRANSIENT ISCHEMIC ATTACK	Initial Entry

**I.ab Start Date:**

Date	Location	User	Value	Reason
Sep-16-2020 15:14:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Jul/UNK/2018	Initial Entry

**I.ab Ongoing:**

Date	Location	User	Value	Reason
Sep-16-2020 15:14:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2018	Initial Entry

**I.ac**

Date	Location	User	Value	Reason
Sep-16-2020 15:14:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Nu 29 mber: Medical Hist CARDIOVASCULA ory Term: R ACCIDENT Start Date: Mar/6/2019 Ongoing: NO End Date:  Mar/UNK/2019	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

***I.ac Line/MH Number:***

Date	Location	User	Value	Reason
Sep-16-2020 15:14:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 29	Initial Entry

***I.ac Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-16-2020 15:14:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> CARDIOVASCULAR ACCIDENT	Initial Entry

***I.ac Start Date:***

Date	Location	User	Value	Reason
Sep-16-2020 15:14:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Mar/6/2019	Initial Entry

***I.ac Ongoing:***

Date	Location	User	Value	Reason
Sep-16-2020 15:14:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date:  Mar/UNK/2019	Initial Entry

***I.ad***

Date	Location	User	Value	Reason
Sep-16-2020 15:15:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Nu 30 mber: Medical Hist RIGHT BUNDLE B ory Term: RANCH BLOCK Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

***I.ad Line/MH Number:***

Date	Location	User	Value	Reason
Sep-16-2020 15:15:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry

***I.ad Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-16-2020 15:15:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> RIGHT BUNDLE BRANCH BLOC K	Initial Entry

***I.ad Start Date:***

Date	Location	User	Value	Reason
Sep-16-2020 15:15:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> UNK/UNK/2017	Initial Entry

***I.ad Ongoing:***

Date	Location	User	Value	Reason
Sep-16-2020 15:15:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Date:**

Date	Location	User	Value	Reason
Aug-12-2020 18:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> Aug/12/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-12-2020 18:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> 177.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-12-2020 18:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-12-2020 18:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> 72.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-12-2020 18:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-12-2020 18:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 24.0	Initial Entry

**7.a**

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1006

Subject No: 10061020

Generated By: pfe.lewissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Aug-12-2020 18:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.3 <b>Temperature Unit:</b> F <b>Temperature Locati on::</b> ORAL CAVI TY	Initial Entry

**7.a Record Identifier:**

Date	Location	User	Value	Reason
Aug-12-2020 18:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Aug-12-2020 18:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> 98.3	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Aug-12-2020 18:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> F	Initial Entry

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Aug-12-2020 18:12:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> Aug/12/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> 226866	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061020

Subject Initials: ---

Generated By: pfe.levissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-13-2020 07:46:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-13-2020 05:13:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-12-2020 18:13:14 (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-12-2020 18:13:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> YES Date of Collection:  Aug/12/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061020

Subject Initials: ---

Generated By: pfe.levisse

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

Aug-13-2020 07:46:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> <b>Sample ID:</b> BLX0FL	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 07:46:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> BLX0FL	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Aug-13-2020 07:47:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> <b>Sample ID:</b> BLX0FM	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 07:47:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> BLX0FM	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Aug-13-2020 07:47:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> <b>Sample ID:</b> BLX0FN	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 07:47:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> BLX0FN	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Aug-13-2020 07:48:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan	<b>Data Entry:</b> <b>Sample ID:</b> BLZ8B7	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

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

Date	Location	User	Value	Reason
Aug-13-2020 07:48:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> BLZ8B7	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Aug-13-2020 07:48:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> <b>Sample ID:</b> BLZ8B8	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 07:48:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> BLZ8B8	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1006

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

Subject No: 10061020

Subject Initials: ---

Generated By: pfe.levissc

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

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**1. Data Origin**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-13-2020 07:47:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Aug-13-2020 05:17:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-12-2020 18:13:25 (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-12-2020 18:13:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> YES Date of Collection:  Aug/12/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
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090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Aug-13-2020 07:47:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> <b>Sample ID:</b> BHV2MM	Initial Entry
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**5.a Sample ID**

Date	Location	User	Value	Reason
Aug-13-2020 07:47:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> BHV2MM	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> Aug/12/2020 11:32	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.lewissc

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

Date	Location	User	Value	Reason
Aug-12-2020 18:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-12-2020 18:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-12-2020 18:13:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-12-2020 18:13:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Emily Wilcox (pfe.ewilcox)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIA RY COLLECTED FOR THIS SUBJ ECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

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**1. Date of Visit**

Date	Location	User	Value	Reason
Nov-06-2020 12:20:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Not Done	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Nov-06-2020 12:20:42 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Not Done	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levisse

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

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

**Subject Initials:** ---

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

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**I. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-13-2020 19:22:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Clo sed	Auto closed by Validation Check: VC_DS001_14_AN
Nov-13-2020 13:51:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 2: Ans wered	Correct per discussion with DM
Nov-13-2020 12:57:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Josee Robillard (pfe.robilj01)	Query 1: Clo sed	Closing as confirmed with stats/spa that the dates are correct as entered given the scenario. SAE with a resolution date of 27AUG2020 however subject withdrawn due to SAE and same time withdrew consent on 16SEP2020 following discussion with PI.
Nov-12-2020 23:56:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Rei ssued: Opene d	DM : Thanks for the response. However, Date of Completion/Discontinuation /Death (16/Sep/2020) is still not between AE start date 25AUG2020 and end date 27AUGP2020 which causing withdrawal of the study vaccine. Please review and update. Else,clarify.
Nov-12-2020 19:46:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 2: Op ened	DMW5372218;'Treatment Date of Completion/Discontinuation /Death' is after 'Date of Completion/Discontinuation /Death' on the Disposition -

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (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:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

				Follow-up eCRF. Please clarify or correct.
Nov-12-2020 14:34:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	Query 1: Ans wered	updated edc
Nov-10-2020 19:04:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Op ened	The discontinuation date of 16SEP2020 should be relative to the AE causing the the withdrawal of the study vaccine, AE start 25AUG2020 and end 27AUGP2020. Please adjust Discontinuation date.
Sep-16-2020 10:48:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry</b> : Sep/1 6/202 0	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-16-2020 10:48:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-17-2020 12:15:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Sep-17-2020 12:14:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-17-2020 12:14:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (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:** 10061020**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:04

Sep-17-2020 12:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-17-2020 12:13:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Sep-17-2020 12:13:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Sep-17-2020 12:13:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> ADVERSE EVENT	Changed Information
Sep-16-2020 10:48:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO LONGER MEETS ELIGIBILIT Y CRITERIA	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Sep-17-2020 12:15:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b>	Changed Information
Sep-17-2020 12:14:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Adverse event 1	Initial Entry
Sep-17-2020 12:14:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b>	Changed Information
Sep-16-2020 10:48:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> No longer inclusion 2	Initial Entry

**Header Text:** c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1006**Subject No:** 10061020**Generated By:** pfe.levissc**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1006) J. Lewis Research, Inc. Foothill Family Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:04[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-13-2020 13:51:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Sep/16/2020	Changed Information
Nov-12-2020 23:52:40 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Nov-12-2020 14:36:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-12-2020 14:36:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	<b>Data Entry:</b> Aug/27/2020	Changed Information
Nov-10-2020 19:04:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ute Frantz (pfe.frantu)	Query 1: Opened	The discontinuation date of 16SEP2020 should be relative to the AE causing the the withdrawal of the study vaccine, AE start 25AUG2020 and end 27AUGP2020. Please adjust Discontinuation date.
Sep-16-2020 10:48:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-16-2020 10:48:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-13-2020 11:15:37 (UTC-07:00) Mountain	ACV0PFEINFP6000	Erica Weaver (pfe.weavee01)	Query 1: Closed	Response satisfies query

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1006

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

**Subject No:** 10061020

**Subject Initials:** ---

**Generated By:** pfe.levissc

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

Time (US & Canada)				
Oct-13-2020 09:45:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-13-2020 09:45:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is ADVERSE EVENT but "Specify Status" is Provided.
Oct-13-2020 09:45:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-13-2020 09:45:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> ADVERSE EVENT	Changed Information
Oct-13-2020 09:35:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (pfe.weavee01)	Query 1: Opened	As per AE form, please update to ADVERSE EVENT if the AE caused study discontinuation and remove status on item 4.
Sep-16-2020 10:48:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO LONGER MEETS ELIGIBIL ITY CRITERIA	Initial Entry

**4. Specify Status:**

Date	Location	User	Value	Reason
Oct-13-2020 09:45:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b>	Changed Information
Sep-16-2020 10:48:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> No longer meets inclusion 2	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levisse

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Created	

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Created	

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

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

**Subject Initials:** ---

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

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Date	Location	User	Value	Reason
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Form Created	

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

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

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**1. Category:**

Date	Location	User	Value	Reason
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-18-2020 14:56:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> CORONARY ARTERY OCCLUSION	Changed Information
Sep-01-2020 04:31:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	reported under AER 2020336034
Aug-31-2020 11:04:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	SAE reported to Pfizer per protocol
Aug-31-2020 05:00:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:WORSENING CORONARY ARTERY DISEASE(Onset date:25Aug2020) is not reported on SAE Report Form but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF.
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan	<b>Data Entry:</b> WORSENING CORONARY ART	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061020

Generated By: pfe.levissc

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

Time (US & Canada)		(pfe.lbevan)	ERY DISEASE	
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4. Start Date Time:

Date	Location	User	Value	Reason
Sep-17-2020 17:23:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 2: Closed	Response satisfies query
Sep-16-2020 14:54:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 2: Answered	SAE narrative updated
Sep-12-2020 06:34:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 2: Opened	Clinical_1) submit fu SAE to reflect angina duration (still reflects 2 wks). Onset date of event needs to reflect start of this non-serious event of angina. Update med hx for baseline angina. 2) RBBB in narrative as previous hx - update med hx.
Sep-06-2020 07:30:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Sep-03-2020 17:48:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	SAE updated with information from Medical Records
Sep-03-2020 09:01:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Reissued:Opened	GPDCLIN: Angina and SOB were added with a start date of 21Aug2020 while the SAE narrative reports onset of angina 2 weeks prior to hospitalization (~12Aug2020). Please reconcile and if needed, please submit a follow-up SAE form with corrections.
Sep-02-2020 14:08:02 (UTC-07:00) Mountain	ACV0PFEINFP6000	Lindsey Bevan	Query 1: Answered	Changed data per query

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Site No: 1006

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

Subject No: 10061020

Subject Initials: ---

Generated By: pfe.lewissc

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Time (US & Canada)		(pfe.lbevan)		
Sep-02-2020 06:16:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Per SAE narrative, subject reported Angina that started 2 weeks prior to hospitalization on 25Aug2020. Please confirm and if correct, please add Angina as a separate non-serious AE with start/stop dates and confirm Inclusion criterion #3 was met.
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Aug/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date Time:  Aug/27/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> 4	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-27-2020 22:34:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Closed	Query closed; will follow for SAE update with the

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**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

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				requested COVID test info
Oct-27-2020 16:20:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 4: Answered	COVID testing not performed. Follow-up SAE form to be faxed to the safety team
Oct-25-2020 19:26:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 4: Opened	COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020336034] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Sep-01-2020 04:31:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Aug-31-2020 23:50:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Closed	Thanks for response. This will be managed internally.
Aug-31-2020 15:36:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE WORSENING CORONARY ARTERY DISEASE: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Aug-31-2020 15:36:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO  Did this serious event result in death?  NO	Changed Information

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			<p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/in capacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
Aug-31-2020 11:08:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	NO PLACE IN ECRF FOR SERIOUS ADVERSE EVENT NUMBER: 2020336034
Aug-31-2020 01:07:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 1: Opened	For AE WORSENING CORONARY ARTERY DISEASE: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Aug-28-2020 18:35:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-28-2020 18:35:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p>	Transcription Error

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			<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/in capacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	
Aug-28-2020 18:34:45 (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.
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE WORSENING CORONARY ARTERY DISEASE: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES Is this serious event life threatening?	Initial Entry

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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.

Date	Location	User	Value	Reason
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Aug-28-2020 18:35:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s) , this event is due to:  OTHER  If Other, specify:  CORONARY ATHEROSCLE ROSIS	Transcription Error
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-17-2020 19:00:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Cl osed	Auto closed by Validation Check: VC_AE001_32
Sep-17-2020 12:15:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: A nswered	Changed data per query
Sep-17-2020 00:28:55 (UTC-07:00) Mountain Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: O pened	DMW4726011;The Latest Action to Study Treatment is DRUG

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(US & Canada)				WITHDRAWN, but the Disposition-Treatment Form Status is not DEATH OR ADVERSE EVENT. Please review and update as appropriate.
Sep-16-2020 15:19:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry</b> : DRUG WI THDRAW N	New Information
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry</b> : NOT APPL ICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 05:58:17 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	outcome updated in SDB to recovered/resolved. issue resolved
Sep-02-2020 06:03:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Reissued:Candidate	to check next SAE listing and monitor update of outcome
Sep-01-2020 11:44:13	ACV0PFEINFP6000	Ty Henry	Query 1: Answered	Original value is correct.

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(UTC-07:00) Mountain Time (US & Canada)		(pfe.thenry)		Updated SAE form submitted.
Sep-01-2020 04:36:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	Query 1: Opened	SAE RECON:AER#2020336034 ,outcome was reported as RECOVERING/RESOLVING in SAE form however,reported as RECOVERED/RESOLVED on AE CRF.Please confirm correct outcome.If safety update is required,please submit ffup. AEM form
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-17-2020 12:14:54 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Changed Information
Aug-28-2020 18:34:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Sep-01-2020 04:31:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.QUITOR)	<b>Data Entry:</b> 2020336034	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> DYSPNEA ON EXERTION	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-21-2020 10:59:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Closed	Response satisfies query
Sep-21-2020 10:58:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-21-2020 10:58:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Aug/25/2020 UNK:UNK	Changed Information
Sep-19-2020 19:06:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (pfe.weavee01)	Query 1: Reissued:Opened	GPDClin: In the SAE report, this symptom started from 25/Aug /2020. If that is correct, please make the corresponding revision here. Form is unfrozen.

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Sep-18-2020 12:33:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Reissued:Candidate	GPDClin: Please unfreeze MHx module, so the site can revise the data.
Sep-18-2020 10:36:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Please unfreeze form for correction
Sep-17-2020 18:58:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 1: Opened	GPDClin: In the SAE report, this symptom started from 25/Aug /2020. If that is correct, please make the corresponding revision here.
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Aug/21/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date Time:  Aug/27/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> 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-02-2020 14:07:10 (UTC-07:00) Mountain	ACV0PFEINFP6000	Lindsey Bevan	<b>Data Entry:</b> NO	Initial Entry

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Time (US & Canada)		(pfe.lbevan)	
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**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Sep-02-2020 15:58:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  CORONARY ATHEROSCLE ROSIS	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:07:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> ANGINA	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-19-2020 10:41:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 1: Closed	Response satisfies query
Sep-18-2020 10:37:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	Confirm Correct
Sep-17-2020 17:47:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 1: Opened	Clinical_as the date of onset of this overall event began on 21 Aug, please submit fu SAE form to update the onset date of the event in the safety database. The dates in the clinical database do not further updates unless not correct.

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Subject No: 10061020

Subject Initials: ---

Generated By: pfe.lewissc

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

Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Aug/21/2020 UNK:UNK	Initial Entry
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date Time:  Aug/27/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> 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-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-02-2020 15:58:59 (UTC-07:00) Mountain	ACV0PFEINFP6000	Lindsey Bevan	<b>Data Entry:</b> NOT RELATED	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1006

Subject No: 10061020

Generated By: pfe.lbevissc

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: ---

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Time (US & Canada)		(pfe.lbevan)	If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  CORONARY ATHEROSCLE ROSIS
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10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-02-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1006

Subject No: 10061020

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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

Subject Initials: ---

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

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**1. Category:**

Date	Location	User	Value	Reason
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-19-2020 10:42:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 1: Closed	Clinical_per discussion w CRA confirmed that a followup SAE form was submitted based on discussion w investigator-- underlying dx updated from worsening CAD to coronary artery occlusion.
Sep-18-2020 10:38:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	NSTEMI not underlying cause for SAE. FU SAE has been submitted
Sep-17-2020 17:25:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 1: Reissued:Opened	Clinical_appreciate the confirmation. If the coronary artery occlusion is the underlying diagnosis for worsening CAD, please update the SAE term in a fu SAE form and add to the AE log.

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Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen

Site No: 1006

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

Subject No: 10061020

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-16-2020 14:55:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	SAE narrative updated
Sep-12-2020 06:26:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 1: Opened	Clinical_In the SAE narrative, 1) NSTEMI not reported. Submit FU SAE to include this diagnosis/assess seriousness if underlying cause of worsening CAD. Update AE log accordingly 2) MVR assess for seriousness and confirm new diagnosis.
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NON-ST ELEVATED MYOCARDI AL INFARCTION	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Aug/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date Time:  Aug/27/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-16-2020 15:19:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> 3	Changed Information
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> 4	Initial Entry

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Header Text: c4591001

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Subject No: 10061020

Generated By: pfe.levissc

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Form Status: Data Complete, Locked, Frozen

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

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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-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-10-2020 06:28:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Sep-09-2020 14:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Sep-09-2020 14:32:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  CORONARY ARTEROSCLEROSIS	New Information
Sep-09-2020 07:18:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	please consider if AE is related to Med Hx condition Coronary Artery Disease, or to

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Header Text: c4591001

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				SAE of Worsening Coronary Artery Disease
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Sep-10-2020 00:10:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Sep-09-2020 14:34:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-09-2020 14:34:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Transcription Error
Sep-09-2020 07:33:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Please clarify no concomitant medication was given for this AE or update as applicable.
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan	<b>Data Entry:</b> YES	Initial Entry

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**Header Text:** c4591001

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**Subject No:** 10061020

**Generated By:** pfe.levissc

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**Subject Initials:** ---

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Time (US & Canada)		(pfe.lbevan)		
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 14:29:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

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**Subject No:** 10061020

**Generated By:** pfe.levissc

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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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**1. Category:**

Date	Location	User	Value	Reason
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> MITRAL VALVE REGURGITATIO N	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Aug/25/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO End Date Time:  Aug/27/2020 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-22-2020 13:31:10 (UTC-07:00) Mountain	ACV0PFEINFP6000	Charu Sabharwal	Query 1: Closed	Response satisfies query

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**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1006**Subject No:** 10061020**Generated By:** pfe.levissc**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

Time (US & Canada)		(pfe.sabhac)		
Sep-22-2020 11:53:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-22-2020 11:53:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> 3	Changed Information
Sep-22-2020 11:01:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (pfe.sabhac)	Query 1: Opened	Clinical_toxicity grade is life threatening/non serious. Please review seriousness and if needed submit a follow-up SAE form/update AE log accordingly.
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> 4	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-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

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**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**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:** ---

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Sep-23-2020 23:56:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ashwini Patil (pfe.patila55)	Query 1: Closed	Per site confirmation
Sep-23-2020 10:41:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Answered	This has already been captured in medical history as Mitral Valve Prolapse
Sep-23-2020 02:51:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	Please review "If not related to study treatment other" field, the following text was indicated in the comment field [Progression of myxomatous mitral valve]. Any symptoms, MH, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[birads02 SDQ=10638]"
Sep-09-2020 14:37:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>	New Information

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Header Text: c4591001

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Subject No: 10061020

Generated By: pfe.levissc

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Form Status: Data Complete, Locked, Frozen

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

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			PROG RESSI ON OF MYXO MATO US MI TRAL VALVE	
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NOT RELAT ED  If Not Relat ed to study t reatment(s), this event is due to:  OTHER	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> YES	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**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

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

Date	Location	User	Value	Reason
Sep-08-2020 14:30:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> NO	Initial Entry

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levisse

**Form:** WITHDRAWAL OF CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

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

**Subject Initials:** ---

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

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**I. Withdrawal of Consent Date :**

Date	Location	User	Value	Reason
Nov-13-2020 19:22:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Clo sed	Auto closed by Validation Check: VC_DS001_20
Nov-13-2020 13:52:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	Query 1: Ans wered	Correct per discussion with DM
Nov-12-2020 19:46:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Op ened	DMW5372194;'Withdrawal of Consent Date' is after 'Date of Completion/Discontinuation '/Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Nov-12-2020 14:34:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Colby Bostock (pfe.cbostock)	<b>Data Entry</b> : Sep/1 6/202 0	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)



**Header Text:** c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1006**Subject No:** 10061020**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[Back to Form](#)**I. Subject Status**

Date	Location	User	Value	Reason
Oct-13-2020 09:45:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Changed Information
Sep-17-2020 12:13:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Changed Information
Sep-16-2020 10:48:44 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Sep-16-2020 10:48:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DISCONTINUED	Initial Entry
Aug-12-2020 18:13:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-12-2020 18:11:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Nov-13-2020 13:51:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/16/2020	Changed Information
Nov-12-2020 14:36:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/27/2020	Changed Information
Oct-13-2020 09:45:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/16/2020	Changed Information
Sep-17-2020 12:13:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/16/2020	Changed Information
Sep-16-2020 10:48:44 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levissc

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

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

**Subject Initials:** ---

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

Time (US & Canada)				
Sep-16-2020 10:48:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/16/2020	Initial Entry
Aug-12-2020 18:13:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/12/2020	Initial Entry
Aug-12-2020 18:11:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/12/2020	Initial Entry

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1006

**Subject No:** 10061020

**Generated By:** pfe.levisse

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Signed, Verified

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

**Subject Initials:** ---

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

[Back to Form](#)

*I. Casebook Signature*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-10-2020 17:57:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Lindsey Bevan (pfe.lbevan)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae3d24\Final\Final On: 01-Apr-2021 04:28 (GMT)