

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisc

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

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/3/2020
----	--------------	---

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10091149]
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: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/3/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MYOCARDIAL INFARCTION]
	Start Date:	Apr/23/2019
	Ongoing:	NO End Date: Apr/23/2019
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GASTROESOPHAGEAL REFLUX DISEASE]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[DEPRESSION]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BENIGN PROSTATIC HYPERPLASIA]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPERLIPIDEMIA]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HYPOTHYROIDISM]
	Start Date:	UNK/UNK/1985
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[OSCILLPSIA]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[INSOMNIA]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[LOW BACK PAIN]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HISTORY OF SPINAL MENINGITIS-NO SYMPTOMS TODAY]
	Start Date:	UNK/UNK/2014
	Ongoing:	NO End Date: UNK/UNK/2018
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[AUGMENTIN INTOLERANCE]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[SLEEP APNEA]
	Start Date:	Mar/31/2012
	Ongoing:	YES

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ACTINIC KERATOSIS]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[HISTORY OF DIVERTICULITIS-NO SYMPTOMS]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[LEFT HIP PAIN]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[LEFT SHOULDER PAIN]
	Start Date:	Aug/19/2011
	Ongoing:	YES

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.q	Line/MH Number:	[17]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ARTHRITIS OF CARPOMETACARPAL JOINT LEFT THUMB]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES
1.r	Line/MH Number:	[18]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BILATERAL IMPACTED CERUM OF EARS-INTERMITTENT]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Clostridium difficile Infection]
	Start Date:	Apr/10/2019
	Ongoing:	NO End Date: May/UNK/2019
1.t	Line/MH Number:	[20]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[TRIGGER FINGER LEFT HAND]
	Start Date:	UNK/UNK/2019
	Ongoing:	NO End Date: Jan/UNK/2020

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

1.u	Line/MH Number:	[21]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diverticulosis]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.v	Line/MH Number:	[22]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[atherosclerosis of aorta]
	Start Date:	Apr/23/2019
	Ongoing:	YES
1.w	Line/MH Number:	[23]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[coronary artery disease]
	Start Date:	Apr/23/2019
	Ongoing:	YES

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/3/2020
2.	Weight:	[164.6]
3.	Unit:	LB
4.	Height:	[72.0]
5.	Unit:	in
6.	Body Mass Index:	[22.3]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.8]
	Unit:	F
	Temperature Location:	ORAL CAVITY

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/3/2020
2.	Randomization Number:	[249592]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
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	[BP9GLP]
5.b	Sample ID	[BP9GLR]
5.c	Sample ID	[BP9GLS]
5.d	Sample ID	[BRTSDH]
5.e	Sample ID	[BRTS80]

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
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	[BP9G3N]
-----	-----------	----------

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/3/2020 11:51
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/22/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.9]
	Unit:	F
	Temperature Location:	ORAL CAVITY

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9G83]
-----	-----------	----------

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/22/2020 10:00
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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/20/2020
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	[BR9FMF]
5.b	Sample ID	[BKYCY0]
5.c	Sample ID	[BKYCTK]

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Signs and Symptoms

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

Symptoms

4.	Symptoms:	
	Was symptom present?	

Symptoms - Other

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB
SELF

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Health Care Utilization

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

Health Care Utilization Other

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

Health Care Utilization

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL - New
Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New
Unscheduled Visit

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY

Form Status: Not Started

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

Subject Initials: ---

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

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

Subject No: 10091149 **Subject Initials:** ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit **Form:** UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

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

Subject No: 10091149 **Subject Initials:** ---

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

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/20/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

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

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB -
New Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB -
New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levissc

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	worsening of diverticulitis	Dec/31/2020 UNK:UNK	NO End Date Time: Jan/2/2021 UNK:UNK	Repeating Pages

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[worsening of diverticulitis]
4.	Start Date Time:	Dec/31/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/2/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [underlying illness]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021051741]

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: MEDICATION ERROR

Form Status: Not Started

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

Subject Initials: ---

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

[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	[]

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATION S	NO	influenza vaccine	Oct/8/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

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

Concomitant Medications

1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[influenza vaccine]
5.	Date:	Oct/8/2020

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Concomitant Medications

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: RADIATION TREATMENT

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

Radiation Treatment

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisc

Form: TRANSFUSIONS

Form Status: Not Started

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

Subject Initials: ---

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

[Back to Form](#)

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

Header Text: c4591001

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

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levissc

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Vaccination

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Contact Outcome

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled **Form:** CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jan/19/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: FURTHER VACCINATION CONFIRMATION

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Jan/19/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

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

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: DEATH DETAILS CODED

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisc

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/15/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/15/2021
----	--------------	--

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Feb/15/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/15/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR6208]
5.b	Sample ID	[BSJ3YL]
5.c	Sample ID	[BSJ4B4]

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/15/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9FFR]
-----	-----------	----------

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/15/2021 09:28
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Mar/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR9FJ7]
-----	-----------	----------

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/8/2021 09:22
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: DATE OF VISIT

Form Status: Not Started

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

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: CONTACT OUTCOME

Form Status: Not Started

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

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - **Form:** DISPOSITION - TREATMENT
Unscheduled

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/20/2020

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levissc

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

[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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Shane Christensen	Approved	Mar-08-2021 20:54:57 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-03-2020 15:54:55 (UTC-07:00) Mountain Time (US & Canada)	Annjanette Kemp (pfe.akemp)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-15-2021 10:39:52 (UTC-07:00) Mountain Time (US & Canada)	Madison Ellis (pfe.mellis)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Shane Christensen	Approved	Mar-08-2021 20:54:57 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

Affidavit:

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

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

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

Madison Ellis	N/A	Mar-08-2021 10:33:52 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
---------------	-----	---	--	-----------------------------------

Affidavit:

N/A

Shane Christensen	Approved	Mar-06-2021 17:06:58 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
-------------------	----------	---	------	--------

Affidavit:

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

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

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

Annjanette Kemp	N/A	Feb-26-2021 15:41:34 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
-----------------	-----	---	--	-----------------------------------

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001**Visit:** Investigator Signature - Unscheduled **Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091149**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12**Affidavit:**

N/A

Shane Christensen	Approved	Feb-22-2021 17:18:12 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
-------------------	----------	---	------	--------

Affidavit:

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

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

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

Madison Ellis	N/A	Feb-15-2021 10:33:04 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
---------------	-----	---	--	-----------------------------------

Affidavit:

N/A

Shane Christensen	Approved	Feb-13-2021 21:24:44 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
-------------------	----------	---	------	--------

Affidavit:

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

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

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

Dylan Owen	N/A	Feb-11-2021 08:18:47 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
------------	-----	---	--	-----------------------------------

Affidavit:

N/A

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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091149**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12

Shane Christensen	Approved	Jan-25-2021 20:51:34 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
<p>Affidavit: By my dated signature below, I, ShaneChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.</p> <p>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.</p> <p>To this I do attest by supplying my user name and password and clicking the button marked Submit below.</p>				
Ricell Ann Piojo	N/A	Jan-25-2021 03:26:41 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
<p>Affidavit: N/A</p>				
Shane Christensen	Approved	Jan-23-2021 20:19:10 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
<p>Affidavit: By my dated signature below, I, ShaneChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.</p> <p>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.</p> <p>To this I do attest by supplying my user name and password and clicking the button marked Submit below.</p>				
Dylan Owen	N/A	Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
<p>Affidavit: N/A</p>				
Shane Christensen	Approved	Oct-29-2020 17:49:35 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed

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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levissc

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

Affidavit:

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

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

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

Dylan Owen	N/A	Oct-27-2020 09:57:18 (UTC-07:00) Mountain Time (US & Canada)		Edit - All signatures invalidated
------------	-----	---	--	-----------------------------------

Affidavit:

N/A

Shane Christensen	Approved	Oct-23-2020 13:51:48 (UTC-07:00) Mountain Time (US & Canada)	BOOK	Signed
-------------------	----------	---	------	--------

Affidavit:

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

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

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-03-2020 15:54:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 15:54:21 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: STAGE 3 COHORTS	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Sep-03-2020 15:54:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<u>Data Entry:</u> OBTAINED Date Written Consent Obtai ned Sep/3/2020	Initial Entry

Header Text: c4591001**Visit:** COHORT_SELECTION**Form Version:** 06-Jul-2020 21:55**Site No:** 1009**Subject No:** 10091149**Generated By:** pfe.levisse**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)**1. Subject ID**

Date	Location	User	Value	Reason
Sep-03-2020 15:54:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10091149	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-03-2020 15:54:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1944	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-03-2020 15:54:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-03-2020 15:54:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NOT HISPANIC OR LATIN O(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 15:54:37 (UTC-07:00)	ACV0PFEINFP6000	Annjanette Kemp	Data Entry: WHITE	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Mountain Time (US &
Canada)

(pfe.akemp)

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 15:54:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-03-2020 15:55:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sep/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-03-2020 15:55:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-03-2020 15:55:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091149**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Sep-03-2020 15:57:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: MYOCARDIAL INFARCTION : Start Date: Apr/23/2019 Ongoing: NO End Date: Apr/23/2019	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 15:57:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Feb-03-2021 16:07:28 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Query closed; will follow for updated Carvedilol indication information.
Feb-03-2021 15:55:42 (UTC-07:00) Mountain Time (US	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: Answered	I did not add HTN to medical history, I amended the indication for the

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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)				medication. Correct as is
Feb-02-2021 09:33:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical Thank you; please also add HTN on this Past Med Hx CRF
Feb-01-2021 15:51:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: Answered	updated on sae form
Jan-27-2021 15:14:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical SAE report states subject is receiving carvedilol for Hypertension; however, HTN is not recorded on past Med hx here or on SAE report. Please update with past med Hx in both locations
Sep-03-2020 15:57:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: MYOCARDIAL INFARC TION	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 15:57:18 (UTC-07:00) Mountain Time (US &	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Apr/23/2019	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Canada)				
---------	--	--	--	--

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 15:57:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NO End Date: Apr/23/2019	Initial Entry

1.b

Date	Location	User	Value	Reason
Sep-03-2020 15:58:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 2 Number: Medical History Term: GASTROESOPH AGEAL REFLUX DISEASE Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091149**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12***1.b Line/MH Number:***

Date	Location	User	Value	Reason
Sep-03-2020 15:58:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 15:58:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: GASTROESOPHAGEAL R EFLUX DISEASE	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 15:58:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/1995	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 15:58:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-03-2020 15:59:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

			Medical History DEPRESSI Term: ON Start Date: UNK/UNK/ 1990 Ongoing: YES	
--	--	--	--	--

I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 15:59:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 15:59:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: DEPRESSION	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 15:59:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/1990	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 15:59:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

l.d

Date	Location	User	Value	Reason
Sep-03-2020 16:00:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 4 Number: Medical History Term: BENIGN PROSTATIC HYPERPLASIA Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091149**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12***I.d Line/MH Number:***

Date	Location	User	Value	Reason
Sep-03-2020 16:00:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:00:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: BENIGN PROSTATIC HYP ERPLASIA	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:00:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/1995	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:00:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-03-2020 16:01:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

			Medical History Term: HYPERLIPIDEMIA Start Date: UNK/UNK/1995 Ongoing: YES	
--	--	--	---	--

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:01:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:01:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: HYPERLIPIDEMIA	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:01:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/1995	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:01:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

If

Date	Location	User	Value	Reason
Sep-03-2020 16:02:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: HYPOTHYROIDISM Start Date: UNK/UNK/1985 Ongoing: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091149**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12***I.f Line/MH Number:***

Date	Location	User	Value	Reason
Sep-03-2020 16:02:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:02:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: HYPOTHYROIDISM	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:02:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/1985	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:02:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Sep-03-2020 16:02:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

			Medical History OSCILLPS Term: IA Start Date: UNK/UNK/ 2017 Ongoing: YES	
--	--	--	--	--

1.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:02:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:02:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: OSCILLPSIA	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:02:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/2017	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:02:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

l.h

Date	Location	User	Value	Reason
Sep-03-2020 16:03:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: Medical History INSOMNI Term: A Start Date: UNK/UNK/ 2000 Ongoing: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091149**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12***I.h Line/MH Number:***

Date	Location	User	Value	Reason
Sep-03-2020 16:03:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:03:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: INSOMNIA	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:03:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/2000	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:03:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

I.i

Date	Location	User	Value	Reason
Sep-03-2020 16:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

			Medical History Term: LOW BACK PAIN Start Date: UNK/UNK/2015 Ongoing: YES	
--	--	--	--	--

1.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: LOW BACK PAIN	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/2015	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:04:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

I,j

Date	Location	User	Value	Reason
Sep-14-2020 08:43:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Line/ 10 MH N umber : Medic HISTORY OF SPI al Hist NAL MENINGITI ory Te S-NO SYMPTOM rm: S TODAY Start UNK/UNK/2014 Date: Ongoi NO ng: End Date: UNK/UNK/2018	Transcription Error
Sep-14-2020 08:42:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Line/ 10 MH N umber : Medic HISTORY OF SPI al Hist NAL MENINGITI ory Te S-NO SYMPTOM rm: S TODAY Start UNK/UNK/2014 Date: Ongoi NO ng: End Date: UNK/UNK/1999	updated

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

<p>Sep-03-2020 16:04:50 (UTC-07:00) Mountain Time (US & Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p>Data Entry: Line/M 10 H Num ber: Medica HISTORY OF SPI l Histor NAL MENINGITI y Term S-NO SYMPTOM : S TODAY Start D UNK/UNK/2014 ate: Ongoin YES g:</p>	<p>Initial Entry</p>
---	------------------------	---------------------------------	--	----------------------

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-20-2020 14:00:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Sep-16-2020 17:39:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Rachel Pugmire (pfe.rpugmire)	Query 1: Answered	unknown etiology. Resolution 2018
Sep-16-2020 12:51:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Spinal meningitis is listed from 2014-2018. Please clarify the underlying etiology of this chronic condition (if infectious, what kind of viral or bacterial infection?)and confirm resolution in 2018 (previously stated as stable, ongoing).

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levissc

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

Sep-03-2020 16:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: HISTORY OF SPINAL MENINGITIS-NO SYMPTOMS TODAY	Initial Entry
---	-----------------	--------------------------------	--	---------------

I.j Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:04:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/2014	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Sep-16-2020 02:06:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	As per site confirmation.
Sep-15-2020 01:25:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 2: Closed	Response satisfies query
Sep-14-2020 08:43:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NO End Date: UNK/UNK/2018	Transcription Error
Sep-14-2020 08:43:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Query 2: Answered	correct as is

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

& Canada)				
Sep-14-2020 08:42:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For Term HISTORY OF SPINAL MENINGITIS-NO SYMPTOMS TODAY End Date is prior to Start Date.
Sep-14-2020 08:42:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NO End Date: UNK/UNK/1999	updated
Sep-14-2020 08:41:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Query 1: Answered	no ongoing symptoms. stable per sub-I.
Sep-14-2020 05:04:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Per response to previous queries, meningitis is infectious and ongoing. Please clarify if disease was considered stable by the investigator as specified in inclusion criterion #3 and if patient receives any systemic treatment, please specify.
Sep-03-2020	ACV0PFEINFP6000	Annjanette	Data Entry:	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

16:04:50 (UTC-07:00) Mountain Time (US & Canada)		Kemp (pfe.akemp)	YES	
---	--	---------------------	-----	--

<i>1.k</i>				
Date	Location	User	Value	Reason
Sep-08-2020 11:50:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: Line/MH 11 Number: Medical History Term: AUGMENTIN INTOLERANCE Start Date: UNK/UNK/2017 Ongoing: YES	Transcription Error
Sep-04-2020 19:15:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: AUGMENTIN INTOLERANCE-OSCILLOPSIA Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

1.k Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 19:15:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 11:50:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: AUGMENTIN INTOLERA NCE	Transcription Error
Sep-04-2020 19:15:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: AUGMENTIN INTOLERA NCE-OSCILLOPSIA	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 19:15:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/2017	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Sep-14-2020 05:01:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	new query will be issued, incorrect place.
Sep-10-2020 11:23:09 (UTC-07:00)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: Answered	infectious

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091149**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 04:12

Mountain Time (US & Canada)				
Sep-10-2020 00:22:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Reissued:Opened	GPDCLIN: Can you please clarify the etiology for this ongoing meningitis (infectious, autoimmune, neoplastic?).
Sep-08-2020 11:50:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Query 1: Answered	ongoing
Sep-07-2020 05:33:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: history of meningitis is listed as ongoing. Please provide an end date or clarify.
Sep-04-2020 19:15:19 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

1.1

Date	Location	User	Value	Reason
Sep-04-2020 19:16:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: SLEEP AP NEA	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

			Start Date:	Mar/31/2012	
			Ongoing:	YES	

1.1 Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 19:16:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 12	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 19:16:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: SLEEP APNEA	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 19:16:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Mar/31/2012	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 19:16:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

1.m

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-04-2020 19:16:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 13 Medical History Term: ACTINIC KERATOSIS Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

1.m Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 19:16:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 19:16:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: ACTINIC KERATOSIS	Initial Entry

1.m Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 19:16:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/2010	Initial Entry

1.m Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 19:16:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

1.n

Date	Location	User	Value	Reason
Sep-04-2020 19:17:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 14	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

				H Number:	
				Medical History Term:	HISTORY OF DIVERTICULITIS-NON-SPECIFIC SYMPTOMS
				Start Date:	UNK/UNK/2010
				Ongoing:	YES
					:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

1.n Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 19:17:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 19:17:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: HISTORY OF DIVERTICULITIS-NO SYMPTOMS	Initial Entry

1.n Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 19:17:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/2010	Initial Entry

1.n Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 19:17:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

1.o

Date	Location	User	Value	Reason
Sep-04-2020 19:18:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numb 15	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			er:	
			Medical History Term:	LEFT HIP PAIN
			Start Date:	UNK/UNK /2014
			Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

1.o Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 19:18:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 19:18:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: LEFT HIP PAIN	Initial Entry

1.o Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 19:18:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/2014	Initial Entry

1.o Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 19:18:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

<i>I.p</i>				
Date	Location	User	Value	Reason
Sep-04-2020 19:18:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 16 mber: Medical Hist LEFT SHOUL ory Term: DER PAIN Start Date: Aug/19/2011 Ongoing: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

1.p Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 19:18:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 19:18:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: LEFT SHOULDER PAIN	Initial Entry

1.p Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 19:18:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Aug/19/2011	Initial Entry

1.p Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 19:18:55 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

1.q

Date	Location	User	Value	Reason
Sep-04-2020 19:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 17	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

			H Number: Medical History Term: ARTHRITIS OF CARPOMETACARPAL JOINT LEFT THUMB Start Date: UNK/UNK/2019 Ongoing: YES	
--	--	--	--	--

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

1.q Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 19:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 17	Initial Entry

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

Date	Location	User	Value	Reason
Feb-22-2021 03:15:01 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Feb-19-2021 15:06:29 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: Answered	confirmed
Feb-14-2021 10:07:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Subject has arthritis and arthralgia involving many joints. Please confirm subject did not receive any prohibited systemic immunosuppressive therapy (exc #13) prior to study entry.
Sep-04-2020 19:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: ARTHRITIS OF CARPO METACARPAL JOINT LEFT THUMB	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

I.q Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 19:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/2019	Initial Entry

I.q Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 19:19:39 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

I.r

Date	Location	User	Value	Reason
Sep-04-2020 19:20:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/M 18 H Num ber: Medical BILATERAL IMPA History CTED CERUM OF Term: EARS-INTERMIT TENT Start D UNK/UNK/2000 ate: Ongoin YES g:	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject No:** 10091149**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12***I.r Line/MH Number:***

Date	Location	User	Value	Reason
Sep-04-2020 19:20:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 18	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 19:20:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: BILATERAL IMPACTED CERUM OF EARS-INTERMITTENT	Initial Entry

I.r Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 19:20:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/2000	Initial Entry

I.r Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 19:20:15 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

I.s

Date	Location	User	Value	Reason
Sep-09-2020 10:39:14 (UTC-07:00)	ACV0PFEINFP6000	Mikaela Jones (pfe mjones)	Data Entry: Line/MH 19	Transcription Error

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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levissc

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

Mountain Time (US & Canada)			Number: Medical History Term: Clostridium difficile Infection Start Date: Apr/10/2019 Ongoing: NO End Date: May/UNK/2019	
Sep-09-2020 09:35:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: Line/MH Number: 19 Medical History Term: Clostridium difficile Infection Start Date: Apr/10/2019 Ongoing: NO	Transcription Error
Sep-09-2020 09:33:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: Line/MH Number: 19 Medical History Term: Clostridium difficile Infection Start Date: Apr/10/2019 Ongoing: YES	Transcription Error
Sep-08-2020 11:51:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: Line/MH Number: 19 Medical History Term: Clostridium difficile Start Date: Apr/10/2019	Transcription Error

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

			Ongoing: YES	
Sep-04-2020 19:20:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 19 Medical History Term: C-DIFF Start Date: Apr/10/2019 Ongoing: YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

I.s Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 19:20:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 19	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 12:27:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Closed	Discrepancy has been closed.
Sep-09-2020 09:33:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Sep-09-2020 09:33:46 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry : Clostridium difficile Infection	Transcription Error
Sep-08-2020 22:10:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 2: Opened	Clarify CLOSTRIDIUM DIFFICILE as follows..Organism only term. Are you reporting TEST? TEST

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

				POSITIVE? INFECTION? If so, edit. Otherwise clarify.Thank you.
Sep-08-2020 14:24:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Clo sed	Discrepancy has been closed.
Sep-08-2020 11:51:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry : Clostr idium diffici le	Transcription Error
Sep-08-2020 11:51:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: An swere d	clostridium difficile
Sep-05-2020 10:33:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Op ened	Clarify C-DIFF as follows...Please specify the medical diagnosis or procedure being reported. If reporting C-DIFF COLITIS or C-DIFF INFECTION or C-DIFF TOXIN TEST or Other, please edit as

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

				such. Otherwise, clarify. Thank you.
Sep-04-2020 19:20:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry : C-DI FF	Initial Entry

1.s Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 19:20:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Apr/10/2019	Initial Entry

1.s Ongoing:

Date	Location	User	Value	Reason
Sep-10-2020 00:16:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Closed	Response satisfies query
Sep-09-2020 10:39:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Mikaela Jones (pfe.mjones)	Data Entry: NO End Date: May/UNK/2019	Transcription Error
Sep-09-2020 09:35:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-09-2020 09:35:56 (UTC-07:00)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: NO	Transcription Error

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Mountain Time (US & Canada)				
Sep-09-2020 04:19:05 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Daria Madar Jacobson (pfe.madard)	Query 1: Opened	GPDCLIN: Please clarify what C. Diff ongoing means or update term/end date as applicable.
Sep-04-2020 19:20:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

It

Date	Location	User	Value	Reason
Sep-04-2020 19:21:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH 20 Number: Medical History Term: TRIGGER FINGER LEFT HAND m: Start Date: UNK/UNK/2019 : Ongoing: NO End Date: Jan/UNK/2020	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

1.t Line/MH Number:

Date	Location	User	Value	Reason
Sep-04-2020 19:21:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 20	Initial Entry

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

Date	Location	User	Value	Reason
Sep-04-2020 19:21:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: TRIGGER FINGER LEFT H AND	Initial Entry

1.t Start Date:

Date	Location	User	Value	Reason
Sep-04-2020 19:21:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: UNK/UNK/2019	Initial Entry

1.t Ongoing:

Date	Location	User	Value	Reason
Sep-04-2020 19:21:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NO End Date: Jan/UNK/2020	Initial Entry

1.u

Date	Location	User	Value	Reason
Feb-11-2021 08:18:47 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Time (US & Canada)			Line/MH Number: 21	
			Medical History Term: diverticulosis	
			Start Date: UNK/UNK/2010	
			Ongoing: YES	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

1.u Line/MH Number:

Date	Location	User	Value	Reason
Feb-11-2021 08:18:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 08:18:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: diverticulosis	Initial Entry

1.u Start Date:

Date	Location	User	Value	Reason
Feb-11-2021 08:18:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: UNK/UNK/2010	Initial Entry

1.u Ongoing:

Date	Location	User	Value	Reason
Feb-11-2021 08:18:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

<i>I.v</i>				
Date	Location	User	Value	Reason
Feb-11-2021 08:19:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 22 Medical History Term: atherosclerosis of aorta Start Date: Apr/23/2019 Ongoing: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

I.v Line/MH Number:

Date	Location	User	Value	Reason
Feb-11-2021 08:19:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 08:19:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: atherosclerosis of aorta	Initial Entry

I.v Start Date:

Date	Location	User	Value	Reason
Feb-11-2021 08:19:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: Apr/23/2019	Initial Entry

I.v Ongoing:

Date	Location	User	Value	Reason
Feb-11-2021 08:19:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: YES	Initial Entry

I.w

Date	Location	User	Value	Reason
Feb-11-2021 08:19:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Nu 23	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (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: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

			mber: Medical Histo coronary arter ry Term: y disease Start Date: Apr/23/2019 Ongoing: YES	
--	--	--	---	--

1.w Line/MH Number:

Date	Location	User	Value	Reason
Feb-11-2021 08:19:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 23	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 08:19:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: coronary artery disease	Initial Entry

1.w Start Date:

Date	Location	User	Value	Reason
Feb-11-2021 08:19:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: Apr/23/2019	Initial Entry

1.w Ongoing:

Date	Location	User	Value	Reason
Feb-11-2021 08:19:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: YES	Initial Entry

090177e196ae3fa4Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:05:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sep/3/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-03-2020 16:05:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: 164.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:05:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-03-2020 16:05:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: 72.0	Initial Entry

5. Unit:

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1009**Subject No:** 10091149**Generated By:** pfe.levisse**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Sep-03-2020 16:05:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: in	Initial Entry
--	-----------------	--------------------------------	--------------------------	---------------

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-03-2020 16:05:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 22.3	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-03-2020 16:05:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Record Identifier: 1 Temperature: 97.8 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 16:05:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 16:05:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: 97.8	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Canada)				
---------	--	--	--	--

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:05:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:05:48 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-03-2020 16:06:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sep/3/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:06:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: 249592	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 16:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 16:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 16:15:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 16:15:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:15:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sample ID: BP9GLP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:15:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: BP9GLP	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 16:15:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sample ID: BP9GLR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:15:57 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: BP9GLR	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 16:16:08 (UTC-07:00)	ACV0PFEINFP6000	Annjanette Kemp	Data Entry: Sample ID: BP9GLS	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Mountain Time (US & Canada)		(pfe.akemp)		
-----------------------------	--	-------------	--	--

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:16:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: BP9GLS	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-03-2020 16:16:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sample ID: BRTSDH	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:16:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: BRTSDH	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-03-2020 16:16:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sample ID: BRTS80	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

5.e Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:16:50 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	<u>Data Entry:</u> BRTS80	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 16:17:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 16:17:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 16:17:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:17:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 16:17:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES Date of Collection: Sep/3/2020	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:17:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sample ID: BP9G3N	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:17:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: BP9G3N	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-03-2020 16:07:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 16:07:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-03-2020 16:07:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-03-2020 16:07:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: Sep/3/2020 11:51	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:07:18 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

6. Body Side:

Date	Location	User	Value	Reason
Sep-03-2020 16:07:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 16:07:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-03-2020 16:07:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 16:07:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-03-2020 16:07:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NO - REACTOGENICITY E -DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Sep-22-2020 14:06:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: Sep/22/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date:

Date	Location	User	Value	Reason
Sep-22-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: Sep/22/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-22-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: Record Identifier:: 1 Temperature: 97.9 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-22-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-22-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: 97.9	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

2.a Unit:

Date	Location	User	Value	Reason
Sep-22-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-22-2020 14:07:47 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Sep-22-2020 14:08:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-22-2020 14:08:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-22-2020 14:13:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 14:08:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 14:08:11 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: YES Date of Collection: Sep/22/2020	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Sep-22-2020 14:13:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: Sample ID: BP9G83	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 14:13:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: BP9G83	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-22-2020 14:09:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-22-2020 14:09:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-22-2020 14:09:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-22-2020 14:09:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: Sep/22/2020 10:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-22-2020 14:09:35 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

6. Body Side:

Date	Location	User	Value	Reason
Sep-22-2020 14:09:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-22-2020 14:09:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-22-2020 14:09:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 14:09:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: YES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Oct-27-2020 13:15:32 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Laurie Hawes (pfe.hawesl01)	Query 1: Closed	Response satisfies query
Oct-27-2020 09:57:38 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: Answered	Changed data per query
Oct-24-2020 10:30:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Prithvee R (pfe.rp21)	Query 1: Opened	As per CRF guidelines, the treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Hence, please complete treatment disposition CRF and update date of EOT to match the date the Visit 3.
Oct-20-2020 19:17:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: Oct/20/2020	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Oct-20-2020 19:18:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-24-2020 08:36:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe.rb01)	Query 1: Closed	Query raised in hidden items
Oct-24-2020 07:02:25 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Prithvee R (pfe rp21)	Query 1: Opened	As per CRF guidelines, the treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Hence, please complete treatment disposition CRF and update date of EOT to match the date the Visit 3.
Oct-20-2020 19:18:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING -
IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1009**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic
South**Subject No:** 10091149**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 04:12

Date	Location	User	Value	Reason
Oct-20-2020 19:22:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-20-2020 19:18:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-20-2020 19:18:09 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: YES Date of Collection: Oct/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-20-2020 19:22:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: Sample ID: BR9FMF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 19:22:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: BR9FMF	Initial Entry

5.b

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Oct-20-2020 19:23:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: Sample ID: BKYCY0	Initial Entry
--	-----------------	------------------------------	--	---------------

5.b Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 19:23:08 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: BKYCY0	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-20-2020 19:24:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: Sample ID: BKYCTK	Transcription Error
Oct-20-2020 19:23:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe.kmarti)	Data Entry: Sample ID: BKYCTK	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

5.c Sample ID

Date	Location	User	Value	Reason
Oct-20-2020 19:24:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-20-2020 19:24:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-20-2020 19:24:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe kmarti)	Data Entry: BKYCTK	Transcription Error
Oct-20-2020 19:23:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding extra spaces or using enter or tab keys.
Oct-20-2020 19:23:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Oct-20-2020 19:23:26 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Krista Marti (pfe kmarti)	Data Entry: BKYCTK	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Canada)				
---------	--	--	--	--

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-27-2020 09:57:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: Oct/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-27-2020 09:57:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-27-2020 09:57:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

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

Subject Initials: ---

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

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

1. Category:

Date	Location	User	Value	Reason
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-25-2021 16:37:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-11-2021 14:11:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: Answered	Original value is correct
Feb-02-2021 09:42:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Feb-02-2021 09:41:41 (UTC-07:00)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	Clinical SAE update (01Feb21) does not report MI

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091149**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Mountain Time (US & Canada)				(23Apr19) or Hypertension (? start) in the SAE Med History section; please update.
Feb-01-2021 15:51:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: Answered	updated on SAE form
Feb-01-2021 15:51:13 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 2: Answered	updated on sae form
Jan-27-2021 15:19:00 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Opened	Clinical Thank you; however SAE report does not specify if sigmoidectomy was performed on 31Dec20 or 01Jan21.
Jan-27-2021 15:18:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Reissued:Opened	CLINICAL Subject undergoing hemicolectomy surgery; CV history would be relevant for surgical risk
Jan-25-2021 15:20:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: Answered	not ongoing or deemed related to SAE, not included per form instructions

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091149**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Jan-25-2021 15:19:07 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 2: Answered	updated SAE form completed
Jan-25-2021 08:01:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical SAE report states subject underwent sigmoidectomy; however, no date is recorded. Please submit a SAE safety update with the date of surgery for the SAE event.
Jan-25-2021 08:00:23 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Past Med Hx shows an even Myocardial Infarction on 23Apr2019; however, SAE med history does not include this. Please review for clinical relevance to surgical procedure risk, and update SAE med Hx if appropriate
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: worsening of diverticulitis	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-21-2021 10:17:43 (UTC-07:00)	ACV0PFEINFP6000	Dylan Owen	Data Entry: Dec/31/2020 UNK:UNK	Initial Entry

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1009**Subject No:** 10091149**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1009) J. Lewis Research, Inc. Foothill Family Clinic South**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:12

Mountain Time (US & Canada)

(pfe.dowen)

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-28-2021 18:50:51 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Feb-26-2021 15:41:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per query
Feb-26-2021 15:41:34 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Annjanette Kemp (pfe.akemp)	Data Entry: NO End Date Time: Jan/2/2021 UNK:UNK	updated per query
Feb-25-2021 16:40:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - Stop date is 03Jan21; however, SAE stop date is 02Jan21. Please review, harmonize reporting, and update stop date in the appropriate location
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: NO End Date Time: Jan/3/2021 UNK:UNK	Initial Entry

6. Toxicity Grade:

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Date	Location	User	Value	Reason
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Feb-02-2021 09:34:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Feb-01-2021 15:50:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Query 2: Answered	It is known that I have no record of a covid test. that is different than knowing that no test was performed.
Jan-27-2021 15:15:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Reissued:Open ed	Clinical – Thank you. If NO hospital COVID test was performed is known, please submit this information on a follow-up SAE form, as pertinent information for

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

				this trial.
Jan-25-2021 15:19:58 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Query 2: Answered	no covid test results in records received
Jan-25-2021 12:16:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 2: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021051741] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Jan-25-2021 07:58:10 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Candidate	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021051741] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Jan-25-2021 03:26:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE worsening of diverticulitis: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: 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	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

			Is this serious event life threatening?	
			NO	
			Other medically important serious event	
			NO	

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

Date	Location	User	Value	Reason
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> underlying illness	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: NOT APPLICABLE	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Canada)				
---------	--	--	--	--

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: YES	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: RECOVERED/RESOLVED	Initial Entry

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

Date	Location	User	Value	Reason
Jan-21-2021 10:17:43 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

Jan-25-2021 03:26:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2021051741	Initial Entry
---	-----------------	-------------------------------------	----------------------------------	---------------

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

Date	Location	User	Value	Reason
Oct-22-2020 19:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Form Created	

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-22-2020 19:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-22-2020 19:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-22-2020 19:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NO	Initial Entry

4. Medication:

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

Date	Location	User	Value	Reason
Oct-22-2020 19:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.downen)	Data Entry: influenza vaccine	Initial Entry

5. Date:

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

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

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

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

Oct-22-2020 19:34:37 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: Oct/8/2020	Initial Entry
---	-----------------	------------------------------	----------------------------------	---------------

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

I. Date of Visit

Date	Location	User	Value	Reason
Feb-15-2021 10:33:04 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: Jan/19/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: FURTHER VACCINATION CONFIRMATION - eCRF
Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

[Back to Form](#)

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

Date	Location	User	Value	Reason
Feb-19-2021 15:03:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-15-2021 19:59:22 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-15-2021 10:33:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-15-2021 10:33:53 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe.mellis)	Data Entry: Participant is willing to return for Vaccination 3 Participant is:	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: FURTHER VACCINATION CONFIRMATION - eCRF
Audit Trail History

Form Status: Data Complete, Frozen

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

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levissc

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

[Back to Form](#)

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-19-2021 15:03:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: Jan/19/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-19-2021 15:03:33 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Feb-15-2021 10:34:24 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: Feb/15/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Feb-15-2021 10:34:35 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: OBTAINED Date Written Consent Obtained Feb/15/2021	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-15-2021 10:34:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: Feb/15/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-15-2021 10:34:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-15-2021 10:34:56 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: COMPLETED	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-15-2021 10:35:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-15-2021 10:35:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-15-2021 10:35:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-15-2021 10:35:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-15-2021 10:35:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe.mellis)	Data Entry: YES Date of Collection: Feb/15/2021	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Feb-15-2021 10:35:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: Sample ID: BR6208	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-15-2021 10:35:27 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: BR6208	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-15-2021 10:35:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: Sample ID: BSJ3YL	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-15-2021 10:35:49 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: BSJ3YL	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-15-2021 10:36:14 (UTC-07:00)	ACV0PFEINFP6000	Madison Ellis	Data Entry: Sample ID: BSJ4B4	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

Mountain Time (US & Canada)		(pfe mellis)		
-----------------------------	--	--------------	--	--

<i>5.c Sample ID</i>				
Date	Location	User	Value	Reason
Feb-15-2021 10:36:14 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: BSJ4B4	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Feb-15-2021 10:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-15-2021 10:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-15-2021 10:37:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-15-2021 10:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-15-2021 10:36:59 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe.mellis)	Data Entry: YES Date of Collection: Feb/15/2021	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Feb-15-2021 10:37:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: Sample ID: BR9FFR	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-15-2021 10:37:12 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: BR9FFR	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-15-2021 10:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-15-2021 10:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-15-2021 10:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-15-2021 10:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: Feb/15/2021 09:28	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-15-2021 10:38:16 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

6. Body Side:

Date	Location	User	Value	Reason
Feb-15-2021 10:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-15-2021 10:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-15-2021 10:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-15-2021 10:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-15-2021 10:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Feb-15-2021 10:38:16 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1009

Subject No: 10091149

Generated By: pfe.levissc

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Date of Visit

Date	Location	User	Value	Reason
Mar-08-2021 10:33:52 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: Mar/8/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

1. Data Origin

Date	Location	User	Value	Reason
Mar-08-2021 10:37:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-08-2021 10:37:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-08-2021 10:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-08-2021 10:37:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-08-2021 10:37:06 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe.mellis)	Data Entry: YES Date of Collection: Mar/8/2021	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

5.a

Date	Location	User	Value	Reason
Mar-08-2021 10:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: Sample ID: BR9FJ7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-08-2021 10:38:20 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: BR9FJ7	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-08-2021 10:37:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-08-2021 10:37:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-08-2021 10:37:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-08-2021 10:37:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: Mar/8/2021 09:22	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-08-2021 10:37:31 (UTC-07:00) Mountain	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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

6. Body Side:

Date	Location	User	Value	Reason
Mar-08-2021 10:37:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Mar-08-2021 10:37:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-08-2021 10:37:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-08-2021 10:37:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-08-2021 10:37:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

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

Subject Initials: ---

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

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

Date	Location	User	Value	Reason
Mar-08-2021 10:37:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Madison Ellis (pfe mellis)	Data Entry: YES	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.levisse

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

[Back to Form](#)

1. Subject Status

Date	Location	User	Value	Reason
Oct-27-2020 09:57:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Sep-03-2020 16:06:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-03-2020 15:55:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Jan-22-2021 09:43:03 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Gladys Noi (pfe.noig)	Query 1: Closed	Response satisfies query
Jan-21-2021 15:50:41 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Query 1: Answered	Changed data per query
Jan-21-2021 03:47:02 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quotr)	Query 1: Opened	SAE RECON:AER#2021051741 worsening of diverticulitis(onset date:31Dec2020)was reported as serious in Safety database but missing in AE CRF. Please confirm

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1009

Subject No: 10091149

Generated By: pfe.lewissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

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

Subject Initials: ---

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

				and update CRF. If safety update is required, submit a follow-up SAE Form.
Oct-27-2020 09:57:18 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/20/2020	Initial Entry
Sep-03-2020 16:06:30 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry
Sep-03-2020 15:55:31 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/3/2020	Initial Entry

090177e196ae3fa4\Final\Final On: 01-Apr-2021 05:20 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1009

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

Subject No: 10091149

Subject Initials: ---

Generated By: pfe.levisse

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

[Back to Form](#)

I. Casebook Signature

Date	Location	User	Value	Reason
Oct-22-2020 11:28:45 (UTC-07:00) Mountain Time (US & Canada)	ACV0PFEINFP6000	Dylan Owen (pfe.dowen)	Data Entry: Click Here to Enable	Initial Entry