

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[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	30 JUN 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001	Form: MAIN INFORMED CONSENT
Visit: COHORT_SELECTION	Form Status: Data Complete, Locked, Frozen, Verified
Form Version: 22-Apr-2020 21:02	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281009	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levisse	

[eCRF Audit Trail History](#)

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Jul/31/2020

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Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[11281009]
2.	Birth Date:	(b) (6)/1954
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: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Jul/31/2020
2.	Erroneous Visit	

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1128**Subject No:** 11281009**Generated By:** pfe.levisse**Form:** INCLUSION/EXCLUSION CRITERIA**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**eCRF Audit Trail History**

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

Inclusion Criteria

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00
1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00
1.d	Inclusion Number:	4
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

Exclusion Criteria

2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00

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Visit: V1_DAY1_VAX1_L

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Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

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Subject Initials: ---

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2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00
2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00
2.f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00

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Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01
2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01
2.k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.l	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2 m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Jul/31/2020
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: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[High Blood Pressure]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[MYOCARDIAL INFARCTION]
	Start Date:	Jan/1/2017
	Ongoing:	NO End Date: Jan/1/2017
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[High Cholesterol]
	Start Date:	UNK/UNK/2001
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anxiety]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bilateral Hip Pain]
	Start Date:	Nov/17/2014
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diabetes mellitus type 2]
	Start Date:	UNK/UNK/1996
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Fluid Retention]
	Start Date:	UNK/UNK/1995
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Angina intermittent]
	Start Date:	UNK/UNK/2017
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Restless Leg Syndrome]
	Start Date:	UNK/UNK/2000
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.lewissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[intermittent Non-productive Cough]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vitamin D Deficiency]
	Start Date:	May/UNK/2020
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Bilateral Hip Replacement]
	Start Date:	Nov/17/2014
	Ongoing:	NO End Date: Nov/17/2014
1.m	Line/MH Number:	[13]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Tobacco Dependency]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.n	Line/MH Number:	[14]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Vasectomy]
	Start Date:	UNK/UNK/1985
	Ongoing:	NO End Date: UNK/UNK/1985

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

1.o	Line/MH Number:	[15]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary Arterial Stent placement]
	Start Date:	Jan/17/2017
	Ongoing:	NO End Date: Jan/17/2017
1.p	Line/MH Number:	[16]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Drug Allergy Diphenhydramine]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Jul/31/2020
2.	Weight:	[128.59]
3.	Unit:	kg
4.	Height:	[190.5]
5.	Unit:	cm
6.	Body Mass Index:	[35.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.3]
	Unit:	C
	Temperature Location:	ORAL CAVITY

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Jul/31/2020
2.	Randomization Number:	[221076]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jul/31/2020
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	[BK8CMW]
5.b	Sample ID	[BK8CMX]
5.c	Sample ID	[BN4YCJ]
5.d	Sample ID	[BN4YCK]
5.e	Sample ID	[BN4YCL]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jul/31/2020
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	[BN4YDJ]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[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:	Jul/31/2020 16:22
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

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Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

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2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Aug/19/2020
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Vital Signs Details

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9W9R]
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/19/2020 15:02
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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BHXNF7]
5.b	Sample ID	[BPR3LJ]
5.c	Sample ID	[BPR3ST]

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Not Done _____ //	Comments
2.	Erroneous Visit	Not Done _____	Comments

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ []
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Not Done _____ //	Comments
2.	Erroneous Visit	Not Done _____	Comments

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ []
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001
Visit: V6_MONTH24_L
Form Version: 22-Apr-2020 21:02
Site No: 1128
Subject No: 11281009
Generated By: pfe.levisse

Form: DATE OF VISIT
Form Status: Data Complete, Frozen, Verified
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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

Date of Visit			
1.	Date of Visit	Not Done _____ //	Comments
2.	Erroneous Visit	Not Done _____	Comments

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ []
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Nov/28/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/28/2020
2.	Erroneous Visit	ERRONEOUS VISIT

COVID-19 Illness Visit

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

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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

Signs and Symptoms

1.	Date of Assessment:	Not Applicable _____ //	Comments
2.	Date of First Symptom Started:	Not Applicable _____ //	Comments
3.	Symptoms Ongoing?	Not Applicable _____	Comments

Symptoms

4.a	Symptoms:	FEVER	
	Was symptom present?	Not Applicable _____	Comments
4.b	Symptoms:	NEW OR INCREASED COUGH	
	Was symptom present?	Not Applicable _____	Comments
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH	
	Was symptom present?	Not Applicable _____	Comments
4.d	Symptoms:	CHILLS	
	Was symptom present?	Not Applicable _____	Comments
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN	
	Was symptom present?	Not Applicable _____	Comments
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL	
	Was symptom present?	Not Applicable _____	Comments
4.g	Symptoms:	NEW OR INCREASED SORE THROAT	
	Was symptom present?	Not Applicable _____	Comments

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Nov/28/2020

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

4.h	Symptoms:	DIARRHEA	
	Was symptom present?	Not Applicable _____	Comments
4.i	Symptoms:	VOMITING	
	Was symptom present?	Not Applicable _____	Comments
Symptoms - Other			
5.	Symptoms - Other Text:	Not Applicable _____ []	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Nov/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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[Form Comments](#)

[eCRF Audit Trail History](#)

Microbiology Specimen

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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Nov/28/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ []
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Nov/28/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ []
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Nov/28/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Not Verified, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Form Comments](#)[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST	
	Occurrence of Visits or Contacts:	Not Applicable	Comments
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM	
	Occurrence of Visits or Contacts:	Not Applicable	Comments
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN	
	Occurrence of Visits or Contacts:	Not Applicable	Comments
1.d	Physician or Healthcare Professional:	URGENT CARE	
	Occurrence of Visits or Contacts:	Not Applicable	Comments
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION	
	Occurrence of Visits or Contacts:	Not Applicable	Comments
1.f	Physician or Healthcare Professional:	OTHER	
	Occurrence of Visits or Contacts:	Not Applicable	Comments

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	Not Applicable	Comments
		[]	

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	Not Applicable	Comments
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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Nov/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Nov/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	Not Applicable _____	Comments
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	Not Applicable _____	Comments
3.	Toxicity Grade:	Not Applicable _____	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE
Nov/28/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Nov/28/2020

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Lab Chemistry Details

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

Lab Result

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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Nov/28/2020

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Laboratory Data Hematology

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

Lab Result

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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 30-Jul-2020 21:27

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Nov/28/2020

Form Version: 30-Jul-2020 21:27

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 30-Jul-2020 21:28

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Nov/28/2020

Form Version: 30-Jul-2020 21:28

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Vital Signs

1.	Date:	//
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Vital Signs Details

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS
Nov/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Nov/28/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Concomitant Medications

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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Nov/28/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Imaging

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

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Illness Visit

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

Visit: POT_COVID_CONVA - New Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY Visit

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Unplanned Assessments

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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Sep/16/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DISPOSITION - FOLLOW-UP

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	Nov/28/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	DEATH
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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still On going	Form Instance
1.	ADVERSE EVENT	1	Myocardial Infarction	Oct/27/2020 UNK:UNK	NO End Date Time: Oct/28/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Pneumonia	Oct/28/2020 UNK:UNK	NO End Date Time: Nov/28/2020 06:00	Repeating Pages

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Myocardial Infarction]
4.	Start Date Time:	Oct/27/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/28/2020 UNK:UNK
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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: [failed cardiac stent]	
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE	
11.	Was a Concomitant Medication given?	Unknown _____	Comments
12.	Was a Non-Drug Treatment given?	NO	
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED	
14.	Did the adverse event cause the subject to be discontinued from the study?	NO	
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020482043]	

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281009**Generated By:** pfe.levisse**Form:** ADVERSE EVENT REPORT**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

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

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pneumonia]
4.	Start Date Time:	Oct/28/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/28/2020 06:00
6.	Toxicity Grade:	4
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? YES Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [infection]

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	FATAL
14.	Did the adverse event cause the subject to be discontinued from the study?	YES
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020482043]

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Medication Error

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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Concomitant Medications

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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Concomitant Medications

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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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?	

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001
Visit: Unplanned Vaccination - Unscheduled **Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281009 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281009 **Subject Initials:** ---
Generated By: pfe.levisse **Generated Time (GMT):** 29-Mar-2021 11:25

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

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

			Comments
1.	Date of Visit	Not Done _____ //	
2.	Erroneous Visit	Not Done _____	Comments

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Informed Consent - Asymptomatic Surveillance

			Comments
1.	Consent Was:	Not Done	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ []
----	-----------	--------------------------------

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	Not Applicable _____ []
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Not Applicable _____ //	Comments
2.	Erroneous Visit	Not Applicable _____	Comments

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Not Applicable	Comments
----	---	----------------	--------------------------

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Not Applicable _____ //	Comments
2.	Primary Reason for Unblinding:	Not Applicable _____	Comments

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Form Comments](#)

[eCRF Audit Trail History](#)

Withdrawal Of Consent

			Comments
1.	Withdrawal of Consent Date :	Not Applicable _____ //	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DEATH DETAILS CODED

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Death Details

1.	Date of Collection / Notification of Death:	Dec/4/2020
----	---	------------

Cause of Death

2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[Pneumonia]

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Nov/28/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Mark Koch	Approved	Mar-08-2021 16:46:39 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, MarkKoch, 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.

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-09-2020 17:07:51 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
1	Dec-09-2020 17:07:51 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Dec-09-2020 17:07:51 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-28-2021 16:10:53 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
1	Jan-28-2021 16:10:53 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
2	Jan-28-2021 16:10:53 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Jan-28-2021 16:10:53 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Jan-28-2021 16:10:53 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Dec-09-2020 17:08:04 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Dec-09-2020 17:08:04 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Dec-09-2020 17:08:04 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-28-2021 16:11:06 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-28-2021 16:11:06 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Jan-28-2021 16:11:06 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Jan-28-2021 16:11:06 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V5_MONTH12_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Jan-28-2021 16:11:06 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
Form	Dec-09-2020 17:08:17 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Dec-09-2020 17:08:17 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Dec-09-2020 17:08:17 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-28-2021 16:11:19 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-28-2021 16:11:19 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Jan-28-2021 16:11:19 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
3	Jan-28-2021 16:11:19 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V6_MONTH24_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Jan-28-2021 16:11:19 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Nov/28/2020

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 10-Dec-2020 02:29
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Status: Data Complete, Not Verified, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 10-Dec-2020 02:29
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Status: Data Complete, Not Verified, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
2	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:29

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

[Back to Form](#)

Item	Date	User	Comment
3	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 10-Dec-2020 02:29
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Status: Data Complete, Not Verified, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4.a	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 10-Dec-2020 02:29
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Status: Data Complete, Not Verified, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4.b	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 10-Dec-2020 02:29
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Status: Data Complete, Not Verified, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4.c	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 10-Dec-2020 02:29
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Status: Data Complete, Not Verified, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4.d	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 10-Dec-2020 02:29
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Status: Data Complete, Not Verified, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4.e	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 10-Dec-2020 02:29
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Status: Data Complete, Not Verified, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4.f	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 10-Dec-2020 02:29
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Status: Data Complete, Not Verified, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4.g	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001	Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Visit: POT_COVID_ILL 1	Form Status: Data Complete, Not Verified, Frozen
Form Version: 10-Dec-2020 02:29	Site Name: (1128) Ventavia Research Group
Site No: 1128	Subject Initials: ---
Subject No: 11281009	Generated Time (GMT): 29-Mar-2021 11:25
Generated By: pfe.levissc	

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Item	Date	User	Comment
4.h	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 10-Dec-2020 02:29
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments
Form Status: Data Complete, Not Verified, Frozen
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4.i	Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

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Item	Date	User	Comment
2	Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

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Item	Date	User	Comment
3	Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

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Item	Date	User	Comment
4	Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
5	Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
6	Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
7	Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
8	Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Nov/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

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Item	Date	User	Comment
9	Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Feb-23-2021 12:00:43 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Feb-23-2021 12:00:43 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Feb-23-2021 12:00:43 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Feb-23-2021 12:00:43 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Feb-23-2021 12:00:43 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments
Nov/28/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Feb-23-2021 12:01:27 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Feb-23-2021 12:01:27 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 22-Apr-2020 21:03
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments
Form Status: Data Complete, Frozen, Verified
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Feb-23-2021 12:01:27 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 22-Apr-2020 21:03
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments
Form Status: Data Complete, Frozen, Verified
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Feb-23-2021 12:01:27 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form Version: 22-Apr-2020 21:03
Site No: 1128
Subject No: 11281009
Generated By: pfe.levissc

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments
Form Status: Data Complete, Frozen, Verified
Site Name: (1128) Ventavia Research Group
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Feb-23-2021 12:01:27 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - Comments
Nov/28/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1.a	Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1.b	Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1.c	Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1.d	Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1.e	Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1.f	Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Dec-2020 02:26

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: HEALTH CARE UTILIZATION - Comments

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - Comments
Nov/28/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Feb-23-2021 12:05:20 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Feb-23-2021 12:05:20 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Feb-23-2021 12:05:20 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Not Verified, Frozen

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Feb-23-2021 12:05:20 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
11	Dec-16-2020 09:15:32 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Unknown

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-29-2021 10:12:42 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
Form	Jan-28-2021 16:11:52 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-29-2021 10:12:42 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
1	Jan-28-2021 16:11:52 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Jan-29-2021 10:12:42 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
2	Jan-28-2021 16:11:52 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE - Comments

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-29-2021 10:13:17 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
Form	Jan-28-2021 16:12:02 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE -
Comments

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-29-2021 10:13:17 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Done
1	Jan-28-2021 16:12:02 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-28-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-28-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Jan-28-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Jan-28-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Jan-28-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-28-2021 16:12:23 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: V201_SURVEIL_CONSENT **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281009 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-28-2021 16:12:23 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: V201_SURVEIL_CONSENT **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281009 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Jan-28-2021 16:12:23 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: V201_SURVEIL_CONSENT **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281009 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
3	Jan-28-2021 16:12:23 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001
Visit: V201_SURVEIL_CONSENT **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments
Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified
Site No: 1128 **Site Name:** (1128) Ventavia Research Group
Subject No: 11281009 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 11:25

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Item	Date	User	Comment
4	Jan-28-2021 16:12:23 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - Comments

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-15-2021 16:46:54 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-15-2021 16:46:54 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DATE OF VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Jan-15-2021 16:46:54 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - Comments

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-22-2021 16:02:33 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: Potential ReVax Initial Contact

Form Version: 10-Dec-2020 02:25

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-22-2021 16:02:33 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-22-2021 16:01:27 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-22-2021 16:01:27 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: TREATMENT UNBLINDED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
2	Jan-22-2021 16:01:27 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
Form	Jan-22-2021 16:02:16 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	Not Applicable

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Item	Date	User	Comment
1	Jan-22-2021 16:02:16 (UTC-06:00) Central Time (US & Canada)	Thea Sonnier (pfe.tsonnier)	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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Mark Koch	Approved	Mar-08-2021 16:46:39 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, MarkKoch, 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.

Jen Vasilio	N/A	Feb-27-2021 12:19:14 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Feb-24-2021 13:47:12 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MarkKoch, 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.

Thea Sonnier	N/A	Feb-23-2021 11:55:57 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-31-2021 11:35:04 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Affidavit:

By my dated signature below, I, MarkKoch, 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.

Thea Sonnier	N/A	Jan-22-2021 16:00:21 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Jan-21-2021 11:46:42 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MarkKoch, 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.

Jen Vasilio	N/A	Jan-13-2021 10:07:19 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

Mark Koch	Approved	Dec-28-2020 10:51:22 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MarkKoch, 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.

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Jen Vasilio	N/A	Dec-13-2020 05:40:45 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Mark Koch	Approved	Dec-11-2020 10:10:49 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MarkKoch, 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.

Jen Vasilio	N/A	Dec-04-2020 15:25:08 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Mark Koch	Approved	Oct-12-2020 10:49:35 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, MarkKoch, 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.

Burt Ray	N/A	Sep-28-2020 13:49:39 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:
N/A

Mark Koch	Approved	Sep-17-2020 17:57:19 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Status: Data Complete, Signed, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Affidavit:

By my dated signature below, I, MarkKoch, 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.

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Jul-31-2020 18:17:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 30 JUN 2020	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 18:17:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I. Consent Was:

Date	Location	User	Value	Reason
Jul-31-2020 18:17:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: OBTAINED Date Written Consent Obtained Jul/31/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Subject ID

Date	Location	User	Value	Reason
Jul-31-2020 18:16:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11281009	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:16:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6)/1954	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Jul-31-2020 18:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Jul-31-2020 18:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NOT HISPANIC OR LATINO(A) O R OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 18:17:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: WHITE	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Jul-31-2020 18:17:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Jul/31/2020	Initial Entry

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1128**Subject No:** 11281009**Generated By:** pfe.levissc**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)*I.a*

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Inclusion Number: Criterion Description: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) Criterion met?: Criterion ID: IN01A00 (For Pfizer only):	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 1	Initial Entry

I.a Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry

I.a Criterion met?

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry
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1.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: IN01A00	Initial Entry

1.b

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Inclusion Number: Criterion Description: Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures Criterion met?: YES Criterion ID: (For Pfizer use only): IN02A00	Initial Entry

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Visit: V1_DAY1_VAX1_L

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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I.b Inclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 2	Initial Entry

I.b Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Participants who are willing and able to comply with all scheduled visits, v accination plan, laboratory tests, lifes tyle considerations, and other study p rocedures	Initial Entry

I.b Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: IN02A00	Initial Entry

I.c

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Inclusi 3 on Nu mber: Criteria Healthy participants who ar on Des e determined by medical hi criptio story, physical examination n: , and clinical judgment of t he investigator to be eligibl e for inclusion in the study	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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			Criteri YES on met ?: Criteri IN03A00 on ID: (For Pf izer us e only) :	
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I.c Inclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 3	Initial Entry

I.c Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Healthy participants who are determi ned by medical history, physical exa mination, and clinical judgment of th e investigator to be eligible for inclus ion in the study	Initial Entry

I.c Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: IN03A00	Initial Entry

I.d

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07	ACV0PFEINFP6000	Jerred	Data Entry:	Initial Entry

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Header Text: c4591001

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Site No: 1128

Subject No: 11281009

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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(UTC-06:00) Central Time (US & Canada)		Downs (pfe.jdowns)	Inclusion Number: 4 Criterion Description: Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol Criterion met?: YES Criterion ID (For Profile use only): IN04A00	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281009

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

I.d Inclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 4	Initial Entry

I.d Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Capable of giving personal signed in formed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

I.d Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: IN04A00	Initial Entry

2.a

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Exclusion Number: Criterion Description: Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281009

Generated By: pfe.leviszc

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

			<p>Criteria NO on met?:</p> <p>Criteria EX01A00 on ID: (For Pfizer use only):</p>	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> NO	Initial Entry

2.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> EX01A00	Initial Entry

2.b

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07	ACV0PFEINFP6000	Jerred	<u>Data Entry:</u>	Initial Entry

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Site No: 1128

Subject No: 11281009

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Subject Initials: ---

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(UTC-06:00) Central Time (US & Canada)		Downs (pfe.jdowns)	Exclusion Number: 2 Criterion Description: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) Criterion met?: NO Criterion ID: (For Pfizer use only): EX02A00	
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2.b Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: EX02A00	Initial Entry

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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2.c

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Exclusion Number: 3 Criterion Description: History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s) Criterion met?: NO Criterion ID: (For Pfizer use only): EX03A00	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

2.c Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: History of severe adverse reaction as sociated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervent ion(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Exclusion Nu 4 mber: Criterion Des Receipt of medicatio cription: ns intended to preve nt COVID-19 Criterion met NO ?: Criterion ID: EX04A00 (For Pfizer us e only):	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1128**Subject No:** 11281009**Generated By:** pfe.levisse**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25**2.d Exclusion Number:**

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Receipt of medications intended to p revent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Exclusi 8 on Nu mber: Criteria Immunocompromised indi on Desc viduals with known or sus ription: pected immunodeficiency, as determined by history a nd/or laboratory/physical e xamination Criteria NO on met ?:	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

			Criteria ID: (For Pfizer use only): EX08A00	
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2.e Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2.e Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Exclusion Number: 10	Initial Entry

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Subject No: 11281009

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

			Criteria Description: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection Criteria Met?: NO Criteria ID (For Pfizer use only): EX10A00	
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2.f Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 10	Initial Entry

2.f Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

2.f Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2.f Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: EX10A00	Initial Entry

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Header Text: c4591001

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Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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2.g

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Exclusion Num 11 ber: Criterion Desc Women who are p reignant or breastfe eding Criterion met?: NO Criterion ID: (EX11A00 For Pfizer use o nly):	Initial Entry

2.g Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Women who are pregnant or breastfe eding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2.g Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

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Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Exclusion Number: 12 Criterion Description: Previous vaccination with any coronavirus vaccine Criterion met?: NO Criterion ID: EX12A00 (For Pfizer use only):	Initial Entry
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2.h Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 12	Initial Entry

2.h Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Previous vaccination with any coronavirus vaccine	Initial Entry

2.h Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2.h Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: EX12A00	Initial Entry

2.i

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time	ACV0PFEINFP6000	Jerred Downs	Data Entry: Exclusion Number: 13	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

(US & Canada)		(pfe.jdowns)	n Number: Criterion Description: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids Criterion met?: NO Criterion ID: (For Pfizer use only): EX13A01
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2.i Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2.i Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Exclusion Number: 15 Criteria Description: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt through out the study Criteria met?: NO Criteria ID: (For Pfizer use only): EX14A01	Initial Entry
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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2.j Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2.j Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: EX14A01	Initial Entry

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Header Text: c4591001

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Site No: 1128

Subject No: 11281009

Generated By: pfe.lewissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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2.k

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Exclusion Number: Criterion Description: Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation Criterion met?: NO Criterion ID: (For Pfizer use only): EX15A01	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

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2.k Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Participation in other studies involvi ng study intervention within 28 days prior to study entry and/or during stu dy participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2.k Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Exclusion 17 Number: Criterion Previous participation in Descripti other studies involving s on: tudy intervention containi ning lipid nanoparticles Criterion NO met?:	Initial Entry

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Header Text: c4591001

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Subject No: 11281009

Generated By: pfe.levissc

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			Criterion ID: (For Pfizer use only): EX16A01	
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2.l Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 17	Initial Entry

2.l Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

2.l Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2.l Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: EX16A01	Initial Entry

2.m

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Exclus 22 ion Nu mber:	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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Site Name: (1128) Ventavia Research Group

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			<p>Criteria Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members</p> <p>Criteria NO on met ?:</p> <p>Criteria EX21A01 on ID: (For Pfizer use only):</p>	
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:27

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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2.m Exclusion Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2.m Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Jul-31-2020 18:18:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: EX21A01	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Jul-31-2020 18:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Jul/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: COMPLETED	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I.a

Date	Location	User	Value	Reason
Jul-31-2020 18:18:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 1 : Medical History T High Blood Pres erm: sure Start Date: UNK/UNK/199 5 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:55 (UTC-06:00) Central 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
Jul-31-2020 18:18:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: High Blood Pressure	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1995	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:18:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.b

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Aug-01-2020 09:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Line/MH Number: 2 Medical History Term: MYOCARDIAL INFARCTION Start Date: Jan/1/2017 Ongoing: NO End Date: Jan/1/2017	Transcription Error
Jul-31-2020 18:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: MI Start Date: Jan/1/2017 Ongoing: NO End Date: Jan/1/2017	Initial Entry

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Header Text: c4591001

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

I.b Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 10:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-01-2020 09:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-01-2020 09:06:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: MYOCARDIAL INFARCTION	Transcription Error
Jul-31-2020 19:36:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify the term MI as follows. Please spell out the abbreviation in the term. If reporting MYOCARDIAL INFARCTION then edit to such. Otherwise clarify the term further. Thank you.
Jul-31-2020 18:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: MI	Initial Entry

I.b Start Date:

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Subject No: 11281009

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Date	Location	User	Value	Reason
Jul-31-2020 18:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Jan/1/2017	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:19:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO End Date: Jan/1/2017	Initial Entry

I.c

Date	Location	User	Value	Reason
Jul-31-2020 18:19:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 3 Medical History Term: High Cholesterol Start Date: UNK/UNK/2001 Ongoing: YES	Initial Entry

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I.c Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:19:52 (UTC-06:00) Central 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
Jul-31-2020 18:19:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: High Cholesterol	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:19:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2001	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:19:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.d

Date	Location	User	Value	Reason
Aug-07-2020 12:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Line/MH Number: 4 Medical History Term: Anxiety Start Date: UNK/UNK/2000 Ongoing: YES	Transcription Error
Jul-31-2020 18:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4 Medical History Term: Anxiety Start Date: UNK/UNK/1999	Initial Entry

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Subject No: 11281009

Generated By: pfe.levissc

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			Ongoing:	YES
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I.d Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:20:08 (UTC-06:00) Central 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
Jul-31-2020 18:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Anxiety	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Aug-13-2020 11:18:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafris06)	Query 1: Closed	Response satisfies query
Aug-07-2020 12:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-07-2020 12:27:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: UNK/UNK/2000	Transcription Error
Aug-04-2020 18:17:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafris06)	Query 1: Opened	Per source, the start year is '2000'. Please verify and update, thanks
Jul-31-2020 18:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1999	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

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I.e

Date	Location	User	Value	Reason
Jul-31-2020 18:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5 Medical History Term: Bilateral Hip Pain Start Date: Nov/17/2014 Ongoing: YES	Initial Entry

I.e Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:20:36 (UTC-06:00) Central 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
Jul-31-2020 18:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Bilateral Hip Pain	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Nov/17/2014	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:20:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.f

Date	Location	User	Value	Reason
Jul-31-2020 18:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6	Initial Entry

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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			Medical History Term: diabetes mellitus type 2 Start Date: UNK/UNK/1996 Ongoing: YES	
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I.f Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:21:49 (UTC-06:00) Central 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
Jul-31-2020 18:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: diabetes mellitus type 2	Initial Entry

I.f Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1996	Initial Entry

I.f Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:21:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.g

Date	Location	User	Value	Reason
Jul-31-2020 18:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 7 Medical History Term: Fluid Retention Start Date: UNK/UNK/1995 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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I.g Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 18:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Fluid Retention	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1995	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:22:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.h

Date	Location	User	Value	Reason
Jul-31-2020 18:22:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: Angina intermittent Start Date: UNK/UNK/2017 Ongoing: YES	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

1.h Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:22:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 18:22:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Angina intermittent	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:22:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2017	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:22:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

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Header Text: c4591001

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Site No: 1128

Subject No: 11281009

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I.i

Date	Location	User	Value	Reason
Jul-31-2020 18:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Numbe 9 r: Medical History Restless Leg Syn Term: drome Start Date: UNK/UNK/2000 Ongoing: YES	Initial Entry

I.i Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 18:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Restless Leg Syndrome	Initial Entry

I.i Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2000	Initial Entry

I.i Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:22:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.j

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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Site Name: (1128) Ventavia Research Group

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Generated Time (GMT): 29-Mar-2021 11:25

Aug-19-2020 17:31:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Line/MH Nu 10 mber: Medical Hist intermittent Non-pr ory Term: oductive Cough Start Date: UNK/UNK/2016 Ongoing: YES	New Information
Aug-19-2020 17:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Line/MH Numb 10 er: Medical History Non-productive Term: Cough Start Date: UNK/UNK/2016 Ongoing: YES	Transcription Error
Aug-19-2020 17:30:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Line/MH Numb 10 er: Medical History Non-productive Term: Cough Start Date: UNK/UNK/2016 Ongoing: YES	New Information (DELETED)
Aug-13-2020 16:57:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Line/MH Numb 10 er: Medical History Non-productive Term: Cough Start Date: UNK/UNK/2016 Ongoing: YES	Changed Information
Aug-04-2020 09:48:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Line/MH Numb 10 er: Medical History Non-essential Term: Cough Start Date: UNK/UNK/2016 Ongoing: YES	Transcription Error
Jul-31-2020 18:23:11 (UTC-06:00) Central	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Initial Entry

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1128

Subject No: 11281009

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Time (US & Canada)			Line/MH Number 10 : Medical History Term: Cough Start Date: UNK/UNK/2016 Ongoing: YES	
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Header Text: c4591001

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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Site Name: (1128) Ventavia Research Group

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1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-19-2020 17:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> 10	Transcription Error
Aug-19-2020 17:30:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> 10	New Information (DELETED)
Jul-31-2020 18:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 10	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 17:42:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 3: Closed	Response satisfies query
Aug-19-2020 17:31:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> intermittent Non-productive Cough	New Information
Aug-19-2020 17:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> Non-productive Cough	Transcription Error
Aug-19-2020 17:30:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	<u>Data Entry:</u> Non-productive Cough	New Information (DELETED)
Aug-19-2020 17:30:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Aug-14-2020 16:28:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 3: Reissued:Opened	Sorry, but I did not see the response or change to my FU query.
Aug-14-2020 15:49:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Query 3: Answered	Changed data per query
Aug-13-2020 18:46:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 3: Reissued:Opened	Thank you for the clarification! A follow-up question:

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Site No: 1128

Subject No: 11281009

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				for this symptom, has there a medical diagnosis been made? If not, can it be more descriptive as appropriate, e.g., intermittent..., chronic..., etc.
Aug-13-2020 16:57:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Aug-13-2020 16:57:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Non-productive Cough	Changed Information
Aug-13-2020 11:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Closed	Response satisfies query
Aug-11-2020 09:05:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Quan Jason Gong (pfe.gongq)	Query 3: Opened	What means "non-essential cough"? Please clarify if it is "nonproductive cough"?
Aug-10-2020 10:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Query 2: Answered	'Non-essential' added to cough in MedHx source, will update eSource to reflect this. Thank you.
Aug-04-2020 18:19:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Opened	Word ' Non-essential' before Cough is not in the source. Please make sure all data should match, thanks
Aug-04-2020 11:09:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 1: Closed	Response satisfies query.
Aug-04-2020 09:48:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-04-2020 09:48:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Non-essential Cough	Transcription Error

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Visit: V1_DAY1_VAX1_L

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Subject No: 11281009

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Aug-03-2020 16:00:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Luke Cunliffe (pfe.cunlil01)	Query 1: Opened	Clinical review: Is there a diagnosis available? Please evaluate and update medex term as appropriate or explain why a diagnosis is not available by providing a response to this query.
Jul-31-2020 18:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Cough	Initial Entry

I.j Start Date:

Date	Location	User	Value	Reason
Aug-19-2020 17:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: UNK/UNK/2016	Transcription Error
Aug-19-2020 17:30:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: UNK/UNK/2016	New Information (DELETED)
Jul-31-2020 18:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2016	Initial Entry

I.j Ongoing:

Date	Location	User	Value	Reason
Aug-19-2020 17:31:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Transcription Error
Aug-19-2020 17:30:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	New Information (DELETED)
Jul-31-2020 18:23:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.k

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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Jul-31-2020 18:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 11 Medical History Term: Vitamin D Deficiency Start Date: May/UNK/2020 Ongoing: YES	Initial Entry
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I.k Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 11	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 18:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Vitamin D Deficiency	Initial Entry

I.k Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: May/UNK/2020	Initial Entry

I.k Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.l

Date	Location	User	Value	Reason
Jul-31-2020 18:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 12 Medical History Term: Bilateral Hip Replacement	Initial Entry

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Header Text: c4591001

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Subject No: 11281009

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			Start Date: Nov/17/2014 Ongoing: NO End Date: Nov/17/2014
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1.1 Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:23:51 (UTC-06:00) Central 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
Jul-31-2020 18:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Bilateral Hip Replacement	Initial Entry

1.1 Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Nov/17/2014	Initial Entry

1.1 Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:23:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO End Date: Nov/17/2014	Initial Entry

1.m

Date	Location	User	Value	Reason
Jul-31-2020 18:24:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 13 : Medical History T Tobacco Depend erm: ency	Initial Entry

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			Start Date:	UNK/UNK/197 0	
			Ongoing:	YES	

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I.m Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:24:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 13	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 18:24:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Tobacco Dependency	Initial Entry

I.m Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:24:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1970	Initial Entry

I.m Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:24:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

I.n

Date	Location	User	Value	Reason
Jul-31-2020 18:24:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 14 : Medical History T Vasectomy erm: Start Date: UNK/UNK/198 5 Ongoing: NO End Date: UNK/UNK/1 985	Initial Entry

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I.n Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:24:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 14	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 18:24:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Vasectomy	Initial Entry

I.n Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:24:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/1985	Initial Entry

I.n Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:24:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO End Date: UNK/UNK/1985	Initial Entry

I.o

Date	Location	User	Value	Reason
Aug-01-2020 09:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Line/MH Number: 15 Medical History Term: Coronary Arterial Stent placement Start Date: Jan/17/2017 Ongoing: NO End Date: Jan/17/2017	Transcription Error
Jul-31-2020 18:25:13	ACV0PFEINFP6000	auto calc	Data Entry:	Initial Entry

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Subject No: 11281009

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(UTC-06:00) Central Time (US & Canada)		(autocalc)	Line/MH Number: 15 Medical History Term: Coronary Arterial Stent Start Date: Jan/17/2017 Ongoing: NO End Date: Jan/17/2017	
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Header Text: c4591001

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Subject No: 11281009

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I.o Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 15	Initial Entry

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

Date	Location	User	Value	Reason
Aug-01-2020 10:22:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Aug-01-2020 09:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-01-2020 09:08:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Coronary Arteria l Stent placement	Transcription Error
Jul-31-2020 19:36:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify CORONARY ARTERIAL STENT as follows...Device only term. Are you reporting INSERTION? REMOVAL? INFECTION OF? Other? Please clarify further and edit. Thank you.
Jul-31-2020 18:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Coronary Arteria l Stent	Initial Entry

I.o Start Date:

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Jul-31-2020 18:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Jan/17/2017	Initial Entry

I.o Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO End Date: Jan/17/2017	Initial Entry

I.p

Date	Location	User	Value	Reason
Jul-31-2020 18:25:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Num 16 ber: Medical Histor Drug Allergy Diphe y Term: ndydramine Start Date: UNK/UNK/2005 Ongoing: YES	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

I.p Line/MH Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:25:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 16	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 18:25:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Drug Allergy Diphenhydramine	Initial Entry

I.p Start Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:25:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: UNK/UNK/2005	Initial Entry

I.p Ongoing:

Date	Location	User	Value	Reason
Jul-31-2020 18:25:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date:

Date	Location	User	Value	Reason
Jul-31-2020 18:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Jul/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Jul-31-2020 18:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 128.59	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Jul-31-2020 18:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Jul-31-2020 18:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 190.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Jul-31-2020 18:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Jul-31-2020 18:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35.4	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

7.a

Date	Location	User	Value	Reason
Jul-31-2020 18:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Record Identifier:: 1 Temperature: 36.3 Temperature Unit: C Temperature Locati on:: ORAL CAVI TY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Jul-31-2020 18:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Jul-31-2020 18:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 36.3	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Jul-31-2020 18:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Jul-31-2020 18:27:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: ORAL CAVITY	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Randomization Date :

Date	Location	User	Value	Reason
Jul-31-2020 18:27:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Jul/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Jul-31-2020 18:27:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: 221076	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Aug-01-2020 08:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-01-2020 08:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-01-2020 08:43:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-01-2020 08:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-01-2020 08:43:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES Date of Collection: Jul/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-01-2020 08:43:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BK8CMW	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Aug-01-2020 08:43:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> BK8CMW	Initial Entry
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5.b

Date	Location	User	Value	Reason
Aug-01-2020 08:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> Sample ID: BK8CMX	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-01-2020 08:43:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> BK8CMX	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-01-2020 08:44:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> Sample ID: BN4YCJ	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-01-2020 08:44:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> BN4YCJ	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-01-2020 08:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	<u>Data Entry:</u> Sample ID: BN4YCK	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

5.d Sample ID

Date	Location	User	Value	Reason
Aug-01-2020 08:44:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BN4YCK	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-01-2020 08:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BN4YCL	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-01-2020 08:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BN4YCL	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Aug-01-2020 08:44:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-01-2020 08:44:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-01-2020 08:44:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-01-2020 08:44:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-01-2020 08:44:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES Date of Collection: Jul/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-01-2020 08:44:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Sample ID: BN4YDJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Aug-01-2020 08:44:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: BN4YDJ	Initial Entry
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jul-31-2020 18:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jul-31-2020 18:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jul-31-2020 18:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jul-31-2020 18:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Jul/31/2020 16:22	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jul-31-2020 18:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jul-31-2020 18:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: LEFT	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

7. Route:

Date	Location	User	Value	Reason
Jul-31-2020 18:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jul-31-2020 18:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Jul-31-2020 18:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Jul-31-2020 18:28:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Aug-19-2020 17:37:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Aug/19/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Symptom:: FAT IG UE	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO
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2.b Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Symptom:: HEADACHE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

2.d

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Symptom:: CH IL LS Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

2.e Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Symptom:: DIA RR HE A Were fever or systemic sym NO ptoms present on the last d ay the Subject Diary was co mpleted?:	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

2.g

Date	Location	User	Value	Reason
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Symptom:: NEW OR WORSE ED MUSC LE PAIN Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?: NO	Initial Entry
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2.g Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Symptom:: NEW OR WORSE NED JOIN T PAIN Were fever or systemic symptoms present on t he last day the Subject Diary was completed? : NO	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

2.h Symptom:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NEW OR WORSENERD JOINT PAI N	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25

Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: REDNESS	Initial Entry
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reaction NO s present on the last day th e Subject Diary was compl eted?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Injection Site Reaction:: PAIN A T INJE CTION	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			SITE	
Were injection site reactions present on the last day the Subject Diary was completed?:				

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?:

Date	Location	User	Value	Reason
Aug-19-2020 17:38:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 30-Jul-2020 21:28**Site No:** 1128**Subject No:** 11281009**Generated By:** pfe.levissc**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Aug-19-2020 17:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Aug/19/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-19-2020 17:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Record Identifier:: 1 Temperature: 97.7 Temperature Unit: F Temperature Locat ion:: ORAL CAVI TY	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-19-2020 17:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Aug-19-2020 17:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: 97.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-19-2020 17:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 30-Jul-2020 21:28

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Aug-19-2020 17:39:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: ORAL CAVITY	Initial Entry
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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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Aug-19-2020 17:40:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-19-2020 17:40:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-19-2020 17:53:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Aug-19-2020 17:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 17:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Aug-19-2020 17:44:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES Date of Collection: Aug/19/2020	Transcription Error
Aug-19-2020 17:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

				provide reason' is missing. Please review and update as appropriate.
Aug-19-2020 17:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-19-2020 17:44:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Transcription Error
Aug-19-2020 17:40:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-19-2020 17:40:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-19-2020 17:53:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Sample ID: BP9W9R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-19-2020 17:53:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: BP9W9R	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-19-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-19-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-19-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-19-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: Aug/19/2020 15:02	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-19-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-19-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: LEFT	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

7. Route:

Date	Location	User	Value	Reason
Aug-19-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-19-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-19-2020 17:40:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Alma Sanchez (pfe.asanchez)	Data Entry: YES	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Visit

Date	Location	User	Value	Reason
Sep-28-2020 13:49:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Burt Ray (pfe.bray2)	Data Entry: Sep/16/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: FAT IG UE	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

2.c Symptom:

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

2.d

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> <u>Symptom::</u> CH ILL S Were fever or systemic sympt oms present on the last day th e Subject Diary was complete d?: NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> <u>Symptom::</u> VO MIT ING Were fever or systemic sym ptoms present on the last da y the Subject Diary was com pleted?: NO	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

2.e Symptom:

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> <u>Symptom::</u> DIA RR HE A <u>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</u> NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	<u>Data Entry:</u> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: NEW OR WORSEN ED MUSC LE PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry
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2.g Symptom:

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NEW OR WORSENERED MUSCLE P AIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Symptom:: NEW OR WORSEN ED JOIN T PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?:	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

2.h Symptom:

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NEW OR WORSENERD JOINT PAI N	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed? :	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 30-Jul-2020 21:30**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25

Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: REDNESS	Initial Entry
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions NO present on the last day the S ubject Diary was completed ?:	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Injection Site Reaction:: PAIN A T INJEC TION SI	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

			TE Were injection site reactions present on the last day the Subject Diary was completed?:	
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5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-04-2020 10:40:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Oct-04-2020 10:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-04-2020 10:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-04-2020 10:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-04-2020 10:40:50 (UTC-06:00) Central 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-04-2020 10:40:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: YES Date of Collection: Sep/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-04-2020 10:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sample ID: BHXNF7	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
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090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Oct-04-2020 10:41:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: BHAXNF7	Initial Entry
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5.b

Date	Location	User	Value	Reason
Oct-04-2020 10:44:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sample ID: BPR3LJ	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-04-2020 10:44:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: BPR3LJ	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-04-2020 10:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Sample ID: BPR3ST	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-04-2020 10:44:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: BPR3ST	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-09-2020 17:07:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Dec-09-2020 17:07:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Jan-28-2021 16:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-28-2021 16:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-28-2021 16:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 16:10:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-09-2020 17:08:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Dec-09-2020 17:08:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: V5_MONTH12_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Jan-28-2021 16:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-28-2021 16:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-28-2021 16:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 16:11:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-09-2020 17:08:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Dec-09-2020 17:08:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry

Header Text: c4591001

Visit: V6_MONTH24_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Jan-28-2021 16:11:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-28-2021 16:11:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-28-2021 16:11:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 16:11:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Nov/28/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**I. Date of Visit**

Date	Location	User	Value	Reason
Feb-24-2021 05:58:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 9: Deleted	Query is invalid or does not apply
Feb-24-2021 05:58:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 10: Deleted	Query is invalid or does not apply
Feb-24-2021 05:58:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 12: Deleted	Query is invalid or does not apply
Feb-24-2021 02:32:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 8: Closed	Response satisfies query
Feb-23-2021 12:01:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 12: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-23-2021 12:01:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 11: Deleted	Close Auto Query
Feb-23-2021	ACV0PFEINFP6000	auto query	Query	Date of Visit is completed

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Nov/28/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25

12:00:17 (UTC-06:00) Central Time (US & Canada)		(autoquery)	11: Candidate	but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Feb-23-2021 11:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 10: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Feb-23-2021 11:55:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 9: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level.
Feb-23-2021 11:55:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 8: Answered	done
Feb-15-2021 14:21:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 8: Opened	Per further notification from Medical Monitor; we need to remove the COVID Illness visit which was originally requested. Please mark as Erroneous and remove the data from within the visit using FORM Level comments of NOT APPLICABLE
Jan-29-2021 15:39:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (pfe.weavee01)	Query 7: Deleted	see comment in forms, subject deceased.
Jan-29-2021 15:32:26	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 6: Clo	Response satisfies query

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Nov/28/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

(UTC-06:00) Central Time (US & Canada)			sed	
Jan-29-2021 14:13:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 4: Clo sed	Auto closed by Validation Check: VC_SV001_04_AN
Jan-29-2021 10:18:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Can didate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Jan-29-2021 10:18:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Ans wered	Changed Information
Jan-29-2021 10:18:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Ans wered	Changed Information
Jan-29-2021 10:18:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry : Nov/2 8/202 0	Changed Information
Jan-28-2021 15:45:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 5: Clo sed	Issued in error
Jan-28-2021 14:50:18 (UTC-06:00)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 6: Op ened	Medical monitor: The Date of Completion/Discontinuation

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Nov/28/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Central Time (US & Canada)				/Death is entered as 28Nov2020. Please consider updating the date of visit to 28Nov2020 since the date entered (14Dec2020) could not be after the date of Completion/Discontinuation /Death
Jan-28-2021 12:20:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 5: Op ened	Please work with the CRA to clear the data from all forms in this visit and add FORM LEVEL comments of Not Applicable after adding the SOD symptoms to the AE form. COVID_A visit should then be marked as ERRONEOUS.
Jan-26-2021 10:54:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Josee Robillard (pfe.robilj01)	Query 4: Rei ssued: Opene d	There cannot be a date later than the date of death. Please remove data from the COVID Illness visit and add COUGH and SHORTNESS OF BREATH as AEs.
Jan-22-2021 08:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 4: Rei ssued: Candi date	Issue added in DM Meeting and Q & A sheet.
Jan-21-2021 10:28:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 4: Ans wered	the symptoms were reported to site after subjects death via subjects family, per medical monitor, this data is to be entered.
Jan-19-2021 01:19:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 4: Rei ssued: Opene d	DM: Please verify subject ended study on 28NOV2020 due to death however COVID ILL visit performed on 14DEC2020 after death details, which cannot possible. Kindly consider updating dates or else clarify. Thank you.

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001				
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History Nov/28/2020				
Form Version: 22-Apr-2020 21:03		Form Status: Data Complete, Frozen, Verified		
Site No: 1128		Site Name: (1128) Ventavia Research Group		
Subject No: 11281009		Subject Initials: ---		
Generated By: pfe.levissc		Generated Time (GMT): 29-Mar-2021 11:25		
Jan-18-2021 12:24:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 4: Ans wered	per previous response: "visit initiated due to medical monitor query"
Jan-18-2021 00:26:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 4: Rei ssued: Opene d	Please clarify why/how visit occurred after Subject ended study on 28Nov2020 due to DEATH. Or update CRFs as required.
Jan-15-2021 08:13:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 4: Ans wered	dropped subjects are eligible for unblinding, therefore the unblinding date will be after completion date
Jan-14-2021 19:33:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 4: Op ened	DMW6841625; 'Date of Visit' is after 'Date of Completion/Discontinuation '/Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Dec-15-2020 03:13:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Del eted	As per response in #4 in swab form
Dec-14-2020 22:27:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 3: Clo sed	Response satisfies query
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Del eted	Close Auto Query
Dec-14-2020	ACV0PFEINFP6000	Thea Sonnier	Query	visit initiated due to medical

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Nov/28/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25

16:51:23 (UTC-06:00) Central Time (US & Canada)		(pfe.tsonnier)	3: Answered	monitor query
Dec-14-2020 16:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Date of Visit is after the Date of Completion/Discontinuation/Death on the Follow-Up Disposition form. Please review and update as appropriate.
Dec-14-2020 16:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-14-2020 16:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-14-2020 16:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry : Dec/14/2020	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Feb-23-2021 11:55:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: ERRONEOUS VISIT	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-14-2020 16:50:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Assessment:

Date	Location	User	Value	Reason
Feb-24-2021 01:49:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Nancy Vedamuthu (pfe.vedamn)	Query 4: Closed	Updated per query
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 11:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Answered	Changed Information
Feb-23-2021 11:57:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Feb-16-2021 11:12:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 4: Opened	Please clear the data from this form and add a FORM LEVEL comment of Not Applicable
Jan-29-2021 15:32:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 2: Closed	Response satisfies query
Jan-29-2021 14:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 3: Closed	Response satisfies query
Jan-29-2021 14:28:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 1: Closed	Response satisfies query
Jan-29-2021 11:50:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-29-2021 11:50:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/28/2020	Changed Information
Jan-29-2021 10:34:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Reissued:Opened	CRF is unfrozen.

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Not Verified, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Jan-29-2021 10:21:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 3: Answered	please unfreeze crf so that site may change date to 28NOV2020
Jan-29-2021 10:21:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	please unfreeze crf so that site may change date to 28NOV2020
Jan-29-2021 10:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	please unfreeze crf so that site may change date to 28NOV2020
Jan-29-2021 10:18:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Date of assessment is not same as Date Visit. Please check and correct.
Jan-29-2021 08:48:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bougus)	Query 2: Opened	Medical monitor: The Date of Completion/Discontinuation /Death is entered as 28Nov2020. Please consider updating the date of assessment to 28Nov2020 since the date entered (14Dec2020) could not be after the date of Completion/ Discontinuation/Death
Jan-28-2021 15:46:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 1: Opened	Please update the Date of Assessment to the date of death since the Death date must be the last date in this subject's CRF
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Dec/14/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 11:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Not Verified, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Oct/28/2020	Initial Entry
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3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 11:57:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Jan-25-2021 14:02:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Closed	Response satisfies query
Jan-22-2021 16:00:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-22-2021 16:00:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO Date of Last Symptom Resolved: Nov/28/2020	Transcription Error
Jan-21-2021 16:27:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	Per source, the date resolved is '28 NOV 2020'. Please verify and update, thanks
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO Date of Last Symptom Resolved: Oct/28/2020	Initial Entry

4.a

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: FEVER Symptom Present Not Applicabl : e	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Not Verified, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Feb-23-2021 11:57:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: FEVER Symptom Present:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: FEVER Symptom Present: NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 11:57:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.b

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREAS ED COUGH Symptom P Not Applicable resent:	Initial Entry
Feb-23-2021 11:58:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREAS ED COUGH Symptom P resent:	Changed Information

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Not Verified, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25

Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom P present: YES	Initial Entry
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4.b Symptoms:

Date	Location	User	Value	Reason
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 11:58:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: Not Applicable	Initial Entry
Feb-23-2021 11:58:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH	Changed Information

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Symptom Present:	
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 11:58:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

4.d

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: CHILLS Symptom Present: Not Applicable	Initial Entry
Feb-23-2021 11:58:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: CHILLS Symptom Present:	Changed Information

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Not Verified, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25

Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry
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4.d Symptoms:

Date	Location	User	Value	Reason
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 11:58:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom Present: Not Applicable	Initial Entry
Feb-23-2021 11:58:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom Present:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Symptom Present: NO	
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4.e Symptoms:

Date	Location	User	Value	Reason
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 11:58:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: Not Applicable	Initial Entry
Feb-23-2021 11:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NEW LOSS OF TASTE OR SMEL L	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 11:58:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms NEW OR INCREASE : D SORE THROAT Symptom Not Applicable Present:	Initial Entry
Feb-23-2021 11:59:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms NEW OR INCREASE : D SORE THROAT Symptom Present:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms NEW OR INCREASE : D SORE THROAT Symptom NO Present:	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

4.g Symptoms:

Date	Location	User	Value	Reason
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NEW OR INCREASED SORE TH ROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 11:59:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: DIARRHEA Symptom Present: Not Applicable	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

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4.h

Date	Location	User	Value	Reason
Feb-23-2021 11:59:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: DIARRHEA Symptom Present:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 11:59:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: VOMITING Symptom Present Not Applicabl : e	Initial Entry
Feb-23-2021 11:59:21 (UTC-06:00) Central Time	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: VOMITING	Changed Information

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

(US & Canada)			Symptom Present:	
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Feb-23-2021 11:59:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 11:59:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 16:52:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Nov/28/2020**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Mar-05-2021 06:17:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Closed	Response satisfies query
Mar-02-2021 15:21:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	site has not received MR and cannot confirm a COVID test was done, however per family of subject, there was a negative COVID done, sometime during hospital stay, not sure which day or which test.
Mar-02-2021 10:08:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Juleen Gayed (pfe.gayedj)	Query 1: Opened	Clin: Please confirm that a swab for COVID-19 was not taken during hospitalisation
Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

4. Assay Code and Description:

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Nov/28/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Date	Location	User	Value	Reason
Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Dec-14-2020 17:09:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Feb-23-2021 12:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:00:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Dec-14-2020 17:08:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 12:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:00:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Dec-14-2020 17:08:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-24-2021 04:18:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloji (pfe.moloim)	Query 1: Closed	Response satisfies query
Feb-23-2021 12:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:00:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Feb-23-2021 12:00:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Feb-16-2021 11:13:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 1: Opened	Please clear the data from this form and add a FORM Level comment of Not Applicable
Dec-14-2020 17:08:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 12:00:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:00:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 17:08:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Site not notified until subject was de ceased	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Feb-23-2021 12:01:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:01:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Dec-14-2020 17:09:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 12:01:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:01:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Dec-14-2020 17:09:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-24-2021 06:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Feb-23-2021 12:01:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:01:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Feb-23-2021 12:01:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Feb-16-2021 11:13:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 1: Opened	Please clear the form and then add a FORM Level comment of Not Applicable
Dec-14-2020 17:09:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 12:01:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:01:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 17:09:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: site not notified of illness until after death	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/28/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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I.a

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or r Contacts: Not Applicable	Initial Entry
Feb-23-2021 12:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts:	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or NO Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-24-2021 04:30:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloji (pfe.moloim)	Query 1: Closed	Response satisfies query
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/28/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

Feb-23-2021 12:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Feb-16-2021 11:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 1: Opened	Please clear this form and add a FORM Level Comment of Not Applicable
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

L.b

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Feb-23-2021 12:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts:	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/28/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:02:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.c

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Feb-23-2021 12:02:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts:	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/28/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

			Occurrence of V NO isits or Contacts:	
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1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:02:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

1.d

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Feb-23-2021 12:02:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts:	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Nov/28/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Not Verified, Frozen**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levissc**Generated Time (GMT):** 29-Mar-2021 11:25***I.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:02:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Feb-23-2021 12:02:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts:	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
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Form Version: 10-Dec-2020 02:26

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Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:02:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.f

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: Not Applicable	Initial Entry
Feb-23-2021 12:03:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts:	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
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Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:03:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 12:03:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:03:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 17:09:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/28/2020 Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Feb-24-2021 03:10:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Astrud van der Merwe (pfe.vandea62)	Query 1: Closed	Response satisfies query
Feb-23-2021 12:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:05:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Feb-23-2021 12:04:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	Changed Information
Feb-16-2021 11:16:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 1: Opened	Please clear this form and add a FORM Level Comment of Not Applicable
Dec-14-2020 17:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

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

Date	Location	User	Value	Reason
Feb-23-2021 12:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:04:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 17:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

3. Toxicity Grade:

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
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Form Status: Data Complete, Not Verified, Frozen

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

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Date	Location	User	Value	Reason
Feb-23-2021 12:05:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry
Feb-23-2021 12:04:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Changed Information
Dec-14-2020 17:10:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: 5	Initial Entry

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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-05-2020 16:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erin McLeod (pfe.emcLeod)	Data Entry: Sep/16/2020	Changed Information
Oct-04-2020 10:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Aug/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-04-2020 10:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-04-2020 10:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: COMPLETED	Initial Entry

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Header Text: c4591001**Visit:** Follow-Up - Unscheduled**Form Version:** 15-Sep-2020 21:53**Site No:** 1128**Subject No:** 11281009**Generated By:** pfe.levisse**Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Dec-17-2020 03:30:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	Response satisfies query
Dec-13-2020 05:40:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Dec-13-2020 05:40:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Nov/28/2020	New Information
Dec-11-2020 05:31:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON: AER#2020482043, the date of death was reported as 28Nov2020 in Safety database but 04Dec2020 in AE CRF. Please confirm correct date of death. If safety update is required, please submit a follow-up form.
Dec-09-2020 17:03:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Dec/4/2020	Transcription Error
Dec-09-2020 15:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Nov/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-09-2020 15:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form: DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

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Dec-09-2020 15:35:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-09-2020 15:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is DEATH but "Specify Status" is Provided.
Dec-09-2020 15:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: DEATH	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Dec-09-2020 15:35:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Transcription Error
Dec-09-2020 15:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: SUBJECT PASSED AWAY AT HO ME AFTER HOSPITALIZATION	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

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Date	Location	User	Value	Reason
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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Date	Location	User	Value	Reason
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Category:

Date	Location	User	Value	Reason
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-08-2020 10:57:50 (UTC-06:00) Central 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
Dec-14-2020 00:45:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Pratiksha Mahadik (pfe.mahadp07)	Query 1: Closed	Closed as per site response.
Dec-13-2020 05:47:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	There is an event of Myocardial Infarction listed in Medical History that was from Jan2017 and ended Jan2017. This is a separate event of Myocardial Infarction.
Dec-10-2020 23:43:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	The AE Myocardial Infarction was reported but is also listed in Medical History. Please clarify if this is a worsening of

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Header Text: c4591001

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Generated By: pfe.levissc

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				the baseline condition, and if so, please consider adding "worsening" to the AE term. AE as baseline conditions should only be reported as AEs if they worsen. "[birads02 SDQ=67569]"
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Myocardial Infarction	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Oct/27/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-04-2021 09:51:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Closed	Response satisfies query
Feb-27-2021 12:19:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-27-2021 12:19:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: NO End Date Time: Oct/28/2020 UNK:UNK	Transcription Error
Feb-24-2021 12:00:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Opened	Medical Monitor_ Pls advice if he recovered date of the MI is 28th Oct, as present in Argus, or

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

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				30th Oct as present in InForm. Thanks
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date Time: Oct/30/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-21-2020 20:01:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Closed	Response satisfies query
Dec-21-2020 11:57:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	Adverse Event log updated and scanned to Complion.
Dec-18-2020 14:22:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Reissued:Opened	Thea, please look the source. The SAE reason line is blank there. Please update as you entered hospitalization above for Q6, thanks
Dec-15-2020 16:29:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	SOURCE WAS PROVIDED
Dec-15-2020 13:04:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 2: Opened	SAE Reason is blank in the AE log. Please provide the source, thanks

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Dec-09-2020 03:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Myocardial Infarction: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>NO</p>	Initial Entry

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

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry
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9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> failed cardiac stent	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-18-2020 14:23:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Closed	Response satisfies query
Dec-16-2020 09:15:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Unknown	Initial Entry
Dec-16-2020 09:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Dec-16-2020 09:15:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry:	Transcription Error
Dec-16-2020 07:31:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Swetha Thangellapally (pfe.thangs22)	Query 1: Reissued:Opened	Unfreeze. Kindly amend. Thanks.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Dec-15-2020 16:28:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	SITE CANNOT AMEND ANSWER. KINDLY UNFREEZE
Dec-15-2020 13:03:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Syed Jafri (pfe.jafri06)	Query 1: Opened	No source for YES in AE log rather No is checked and UNK mentioned. Please provide the proper source, thanks
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-11-2020 05:28:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Closed	Response satisfies query
Dec-09-2020 17:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Dec-09-2020 17:03:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	<u>Data Entry:</u> RECOVERED/RESOLV ED	Transcription Error
Dec-09-2020 03:47:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 3: Opened	SAE RECON:AER#2020482043,outcome was reported as RECOVERED/RESOLVED to Safety DB however, recorded as RECOVERED/RESOLVED WITH SEQUELAE on AE CRF. Please confirm correct outcome. If safety

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Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1128**Subject No:** 11281009**Generated By:** pfe.levissc**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25

				update is required, please submit a follow-up form.
Dec-08-2020 11:01:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-08-2020 11:01:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: RECOVERED/RESOLVED WITH SEQUELAE	Transcription Error
Dec-08-2020 11:00:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Myocardial Infarction: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Dec-08-2020 11:00:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-08-2020 11:00:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NOT RECOVERED/NO T RESOLVED	Transcription Error
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Myocardial Infarction: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: UNKNOWN	Initial Entry

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

Date	Location	User	Value	Reason
Dec-08-2020 11:00:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Transcription Error
Dec-08-2020 10:57:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

Header Text: c4591001

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Generated By: pfe.levissc

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15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-09-2020 03:44:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020482043	Initial Entry

Header Text: c4591001

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

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1. Category:

Date	Location	User	Value	Reason
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-02-2021 07:38:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Rose Madelein (pfe.rose19)	Query 4: Closed	Response satisfies query
Feb-27-2021 12:22:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 4: Answered	SITE HAS NOT BEEN MADE AWARE THIS EVENT WAS COVID PNEUMONIA. PER PI PNEUMONIA WAS RELATED TO INFECTION, HOWEVER SITE HAS NO RECORDS THAT STATE COVID, THEREFORE TERM CANNOT BE UPDATED TO SUCH.
Feb-15-2021 14:25:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Mary Campbell (pfe.campbm25)	Query 4: Opened	For correct attribution of Pneumonia; please update AE term to COVID Pneumonia

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				or Pneumonia secondary to COVID-19 else clarify as per guidance from Clinical Monitor.
Dec-15-2020 00:38:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 3: Closed	Response satisfies query
Dec-15-2020 00:38:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 2: Closed	Response satisfies query
Dec-15-2020 00:38:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Closed	Response satisfies query
Dec-14-2020 16:50:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 3: Answered	Changed data per query
Dec-14-2020 16:49:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 2: Answered	Changed data per query
Dec-14-2020 16:49:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Dec-13-2020 16:05:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 3: Opened	Medical monitor: Please the data should still be captured on the appropriate CRF pages (as for any late data, we will still capture it and not ignore it) but a swab will not be required
Dec-13-2020 16:03:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 2: Opened	Clin: Despite telehealth visit was not done, please complete the potential COVID-19 Illness Visit CRF forms with all information available. Should be

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Subject No: 11281009

Generated By: pfe.levissc

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Subject Initials: ---

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				captured only on the SOD CRF form and a NASAL SWAB will not be collected
Dec-13-2020 16:02:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (pfe.bogus)	Query 1: Opened	Clin: Per Prot Sect 8.13., potential COVID-19 related PNEUMONIA should have please triggered a COVID Illness Visit irrespective of perceived etiology or clinical significance. Please complete the COVID-19 CRF forms.
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Pneumonia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Oct/28/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO End Date Time: Nov/28/2020 06:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: 4	Initial Entry

7. Is the adverse event serious?

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Subject No: 11281009

Generated By: pfe.levissc

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If Yes, NOTIFY PFIZER IMMEDIATELY.

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

Date	Location	User	Value	Reason
Dec-09-2020 03:45:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Pneumonia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? YES Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? YES Other medically important serious	Initial Entry

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Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

			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
Dec-08-2020 10:59:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: NO	Initial Entry

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Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levisse

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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Dec-11-2020 02:16:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 1: Closed	Response satisfies query
Dec-09-2020 17:09:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Dec-08-2020 22:30:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW6402540;The outcome of this AE is selected as FATAL, but there are no Disposition eCRFs with a 'Status' of DEATH. Please review and update as appropriate.
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry : FATAL	Initial Entry

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

Date	Location	User	Value	Reason
Dec-09-2020 00:55:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Vikas Joshi (pfe.joshiv22)	Query 1: Closed	Response satisfies query
Dec-08-2020 11:01:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	More than 1 AE for this patient has "Did the adverse event cause the subject to be discontinued from the study?" marked

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Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

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Form Status: Data Complete, Frozen, Verified

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				as 'Yes'.
Dec-08-2020 10:59:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: YES	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Dec-09-2020 03:45:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Data Entry: 2020482043	Initial Entry

Header Text: c4591001**Visit:** V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-29-2021 14:18:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: C losed	Auto closed by Validation Check: VC_SV001_05
Jan-29-2021 10:12:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: A nswered	Changed data per query
Jan-29-2021 10:12:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entr y: Not Done	Initial Entry
Jan-29-2021 02:54:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: O pened	DMW7050039;Date of Visit is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Jan-28-2021 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entr y: Not Applic able	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Jan-29-2021 10:12:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Jan-28-2021 16:11:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

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Subject Initials: ---

Generated By: pfe.levissc

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I. Consent Was:

Date	Location	User	Value	Reason
Jan-29-2021 14:18:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_16
Jan-29-2021 10:13:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: Answered	Changed data per query
Jan-29-2021 10:13:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Done	Initial Entry
Jan-29-2021 02:05:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7050049; Consent Obtained is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Jan-28-2021 16:12:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Jan-28-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-28-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-28-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 16:12:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled 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: 1128

Site Name: (1128) Ventavia Research Group

Subject No: 11281009

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 11:25

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1. Data Origin

Date	Location	User	Value	Reason
Jan-28-2021 16:12:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-28-2021 16:12:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-28-2021 16:12:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Jan-28-2021 16:12:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form:** DATE OF VISIT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1128**Site Name:** (1128) Ventavia Research Group**Subject No:** 11281009**Subject Initials:** ---**Generated By:** pfe.levisse**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-27-2021 10:09:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: C losed	Response satisfies query
Jan-26-2021 15:49:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Query 1: A nswered	Subject is deceased. Visit is not applicable.
Jan-26-2021 12:26:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: O pened	DMW6864383;Date of Visit is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify
Jan-15-2021 16:46:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entr y: Not Applic able	Initial Entry

2. Erroneous Visit

Date	Location	User	Value	Reason
Jan-15-2021 16:46:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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

Date	Location	User	Value	Reason
Jan-22-2021 16:02:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-22-2021 16:01:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-22-2021 16:01:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I. Withdrawal of Consent Date :

Date	Location	User	Value	Reason
Jan-22-2021 16:02:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Thea Sonnier (pfe.tsonnier)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I. Date of Collection / Notification of Death:

Date	Location	User	Value	Reason
Jan-17-2021 17:46:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 4: Closed	Response satisfies query
Jan-13-2021 10:07:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 4: Answered	per AE log, the data has been entered below
Jan-06-2021 13:45:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 4: Opened	ClinQuery: Is cause of death information available? If so, please update Cause of Death field of DEATH DETAILS form as appropriate. Further guidance is available in section 8.67 of the CCR (V11).
Jan-05-2021 18:43:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Hao Hu (pfe.huh17)	Query 4: Candidate	ClinQuery: Is cause of death information available? If so, please update Cause of Death field of DEATH DETAILS form as appropriate. Further guidance is available in section 8.67 of the CCR (V11).
Dec-14-2020 08:03:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 3: Closed	SAE query present on FUP form
Dec-13-2020 05:42:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 3: Answered	date notified/date info collected is 04DEC2020.
Dec-13-2020 05:40:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 28/Nov/2020. Please review and update as appropriate

090177e196ae4010\Final\Final On: 01-Apr-2021 05:29 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Dec-09-2020 18:43:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Closed	Response satisfies query
Dec-09-2020 17:03:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Dec-09-2020 15:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection / Notification of Death is greater than the Date of Completion/Discontinuation /Death on the Disposition form 28/Nov/2020. Please review and update as appropriate
Dec-08-2020 08:45:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Query 1: Answered	Once the death certificate has been received we will try to obtain medical records.
Dec-07-2020 17:10:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (pfe.castig19)	Query 1: Opened	CLINQUERY_ Per report, the subject was hospitalized on 27Oct2020. Kindly provide further details on Med records/hospitalization course. And, if covid testing was performed, please specify the result in a FU report. Thank you.
Dec-04-2020 15:25:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Dec/4/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Jan-13-2021 10:07:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Cause of Death PRIMARY CAUSE h Status: OF DEATH Cause of Death Pneumonia h:	Initial Entry

2.a Cause of Death Status:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

Jan-13-2021 10:07:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: PRIMARY CAUSE OF DEATH	Initial Entry
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2.a Cause of Death:

Date	Location	User	Value	Reason
Jan-13-2021 10:07:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jen Vasilio (pfe.jvasilio)	Data Entry: Pneumonia	Initial Entry

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1128**Subject No:** 11281009**Generated By:** pfe.levisse**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Verified**Site Name:** (1128) Ventavia Research Group**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:25[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Dec-09-2020 15:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Oct-04-2020 10:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: FOLLOW-UP	Initial Entry
Jul-31-2020 18:27:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Jul-31-2020 18:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Dec-13-2020 05:40:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/28/2020	New Information
Dec-09-2020 17:03:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Dec/4/2020	Transcription Error
Dec-09-2020 15:35:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Nov/28/2020	Initial Entry
Oct-05-2020 16:09:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/16/2020	Changed Information
Oct-04-2020 10:47:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Aug/19/2020	Initial Entry
Jul-31-2020 18:27:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/31/2020	Initial Entry
Jul-31-2020 18:18:19 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Jul/31/2020	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1128

Subject No: 11281009

Generated By: pfe.levissc

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

(US & Canada)				
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Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1128

Subject No: 11281009

Generated By: pfe.levisse

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1128) Ventavia Research Group

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:25

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I. Casebook Signature

Date	Location	User	Value	Reason
Sep-17-2020 16:51:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Jerred Downs (pfe.jdowns)	Data Entry: Click Here to Enable	Initial Entry